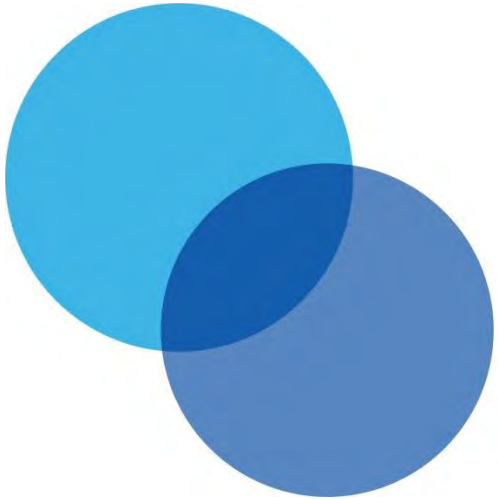


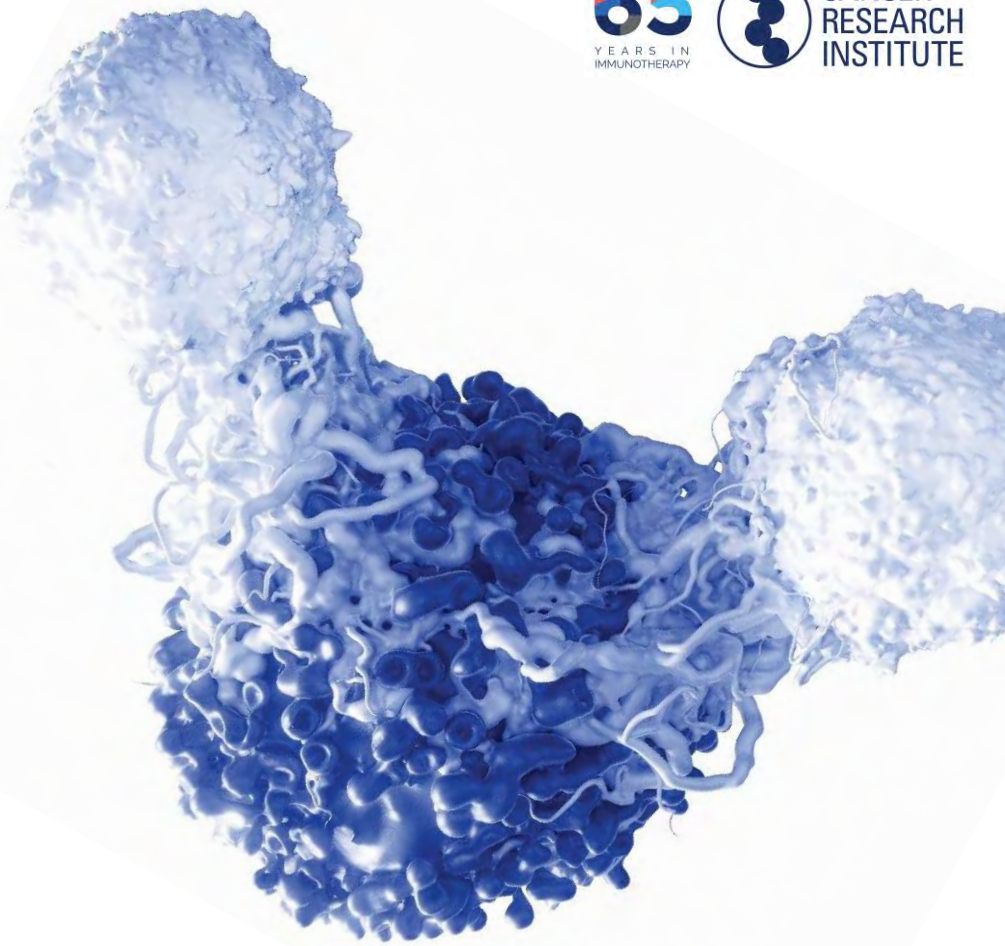
CANCER RESEARCH INSTITUTE

IMMUNOTHERAPY PATIENT SUMMIT

San Diego October 27, 2018

65 YEARS IN IMMUNOTHERAPY

CANCER RESEARCH INSTITUTE



Brian Brewer

Cancer Research Institute

WELCOME

CANCER RESEARCH INSTITUTE
IMMUNOTHERAPY PATIENT SUMMIT

Special thanks

65 YEARS IN IMMUNOTHERAPY

CANCER RESEARCH INSTITUTE

SPECIAL THANKS
To our San Diego partners

if Immunotherapy Foundation

UC San Diego SCHOOL OF MEDICINE

CANCER RESEARCH INSTITUTE IMMUNOTHERAPY PATIENT SUMMIT

Our Sponsors

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CANCER RESEARCH INSTITUTE
IMMUNOTHERAPY
PATIENT SUMMIT

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Our Educational Partners

Thank you to those who helped promote the summit

- Addario Lung Cancer Foundation
- American Cancer Society
- But Doctor I Hate Pink (Ann Silberman)
- Cancer Support Community
- CancerCare
- Colorectal Cancer Alliance
- Fight Colorectal Cancer
- FORCE
- Imerman Angels
- Leukemia & Lymphoma Society
- LUNGevity Foundation
- Let Life Happen (Barbara Jacoby)
- Patient Empowerment Network
- SHARE
- UC San Diego Moores Cancer Center
- Us TOO
- Young Survival Coalition

Speakers

Scientific Experts

Ezra Cohen, M.D.
Moores Cancer Center at UC San Diego Health

Aaron M. Miller, M.D., Ph.D.
Moores Cancer Center at UC San Diego Health

Sandip P. Patel, M.D.
Moores Cancer Center at UC San Diego Health

Rebecca A. Shatsky, M.D.
Moores Cancer Center at UC San Diego Health

Patient Experts

Dan Engel
Melanoma

Kristen Kleinhofer
Acute Lymphoblastic Leukemia (ALL)

Rikki Rockett
Oral Cancer

Rebecca S.
Breast Cancer

Schedule of Events

65 YEARS IN IMMUNOTHERAPY

CANCER RESEARCH INSTITUTE

9:00 am	Registration and networking
10:00 am	Program commences
	WELCOME Brian Brewer
10:15 am	**HEAR FROM THE EXPERTS** Presentation: Immunotherapy Basics Ezra Cohen, M.D.
10:30 am	Panel: Research Updates Moderator Ezra Cohen, M.D. Panelists Aaron M. Miller, M.D., Ph.D. Sandip P. Patel, M.D. Rebecca A. Shatsky, M.D.
11:30 am	**PATIENT PERSPECTIVE** Choose Hope, a message from Kristin Kleinhofer, leukemia survivor
12:00 pm	Lunch and networking
1:00 pm	**LEARN ABOUT CLINICAL TRIALS** Brian Brewer
1:15 pm	**IMMUNOTHERAPY PATIENT PANEL** Moderator Brian Brewer Panelists Dan Engel Rikki Rockett Rebecca S.
2:00 pm	Transition Break
2:15 pm	**BREAKOUT SESSIONS** Your choice of a moderated, deeper-dive Q&A with our experts **General Immunotherapy** Ezra Cohen, M.D. **Breast Cancer** Rebecca A. Shatsky, M.D. **Lung Cancer** Sandip P. Patel, M.D. **Gastrointestinal Cancers** Aaron M. Miller, M.D., Ph.D.
3:15 pm	Program closes
9:00 am – 4:00 pm	**CLINICAL TRIAL NAVIGATOR APPOINTMENTS** Appointments are available all day. If you didn't pre-register, but you are interested in scheduling an appointment, please visit the Clinical Trial Navigator desk for more information.

After the Summit

You will receive two emails after the summit:

1. **A survey** to share your feedback on the summit as well as insights into future programming.

2. **Information** from the summit day, including this presentation and instructions on how to use our Clinical Trial Finder service.

Immunotherapy 101

65 YEARS IN IMMUNOTHERAPY

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Ezra Cohen, M.D., F.R.C.P.S.C., F.A.S.C.O.

Professor of Medicine

Associate Director, Translational Science

Co-Director, San Diego Center for Precision Immunotherapy

Moores Cancer Center

University of California, San Diego School of Medicine

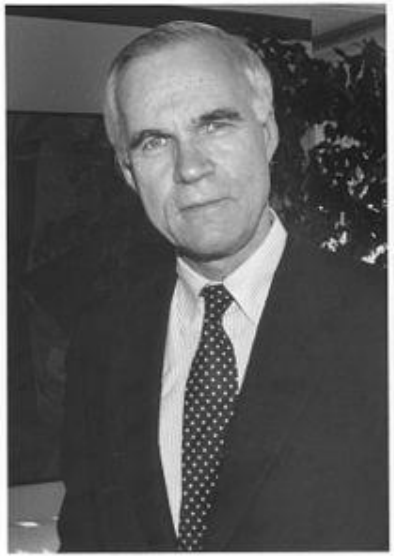
UC San Diego
MOORES CANCER CENTER

UC San Diego
SCHOOL OF MEDICINE

Origin & Revival of Immunotherapy

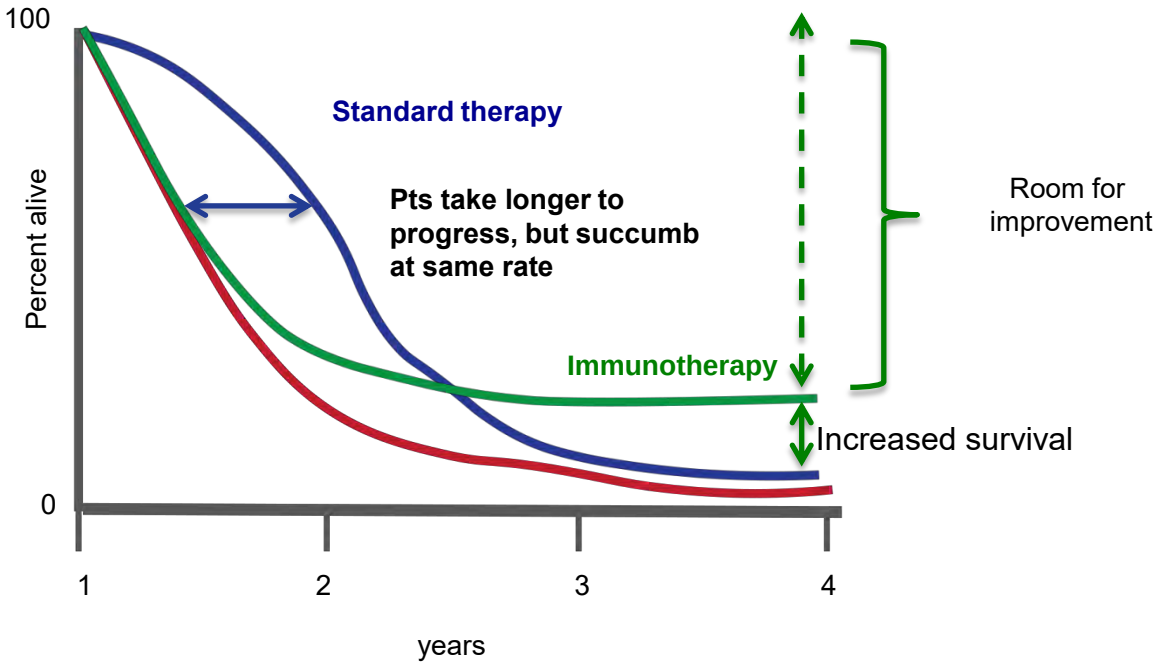
1890s:
William B. Coley

1900s:
Paul Ehrlich



1960s:
Lloyd J. Old

Immunotherapy: A Potential Cure?



The Immune System At a Glance

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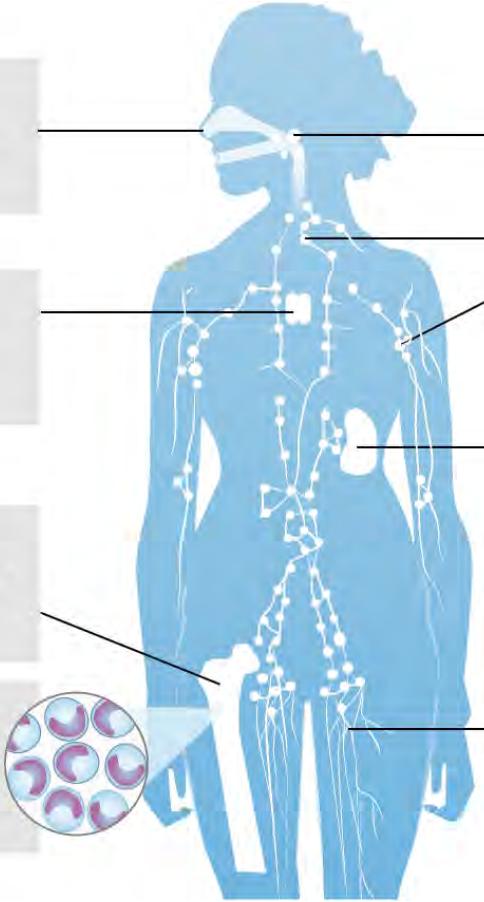
Nose
Hairs and mucus trap foreign particles and prevent them from entering the body

Thymus
Small organ located just behind the breastbone where T cells mature (the "T" is for thymus)

Bone marrow
Tissue in the center of bones that is responsible for making blood cells, including white blood cells

White blood cells
White blood cells—including macrophages, dendritic cells, and lymphocytes—are the cellular actors of immunity



Tonsils
Structures at the back of the throat that sample bacteria and viruses that enter the body through the mouth or nose

Lymph nodes
Small, bean-shaped structures located throughout the body that filter lymph fluid; where immune cells are alerted to the presence of pathogens or cancer

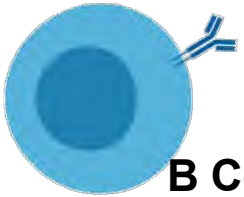
Spleen
Fist-sized organ located in the upper-left part of the abdomen, containing white blood cells that fight infection and cancer

Lymphatic vessels
Thin-walled tubes that collect and transport lymph fluid throughout body

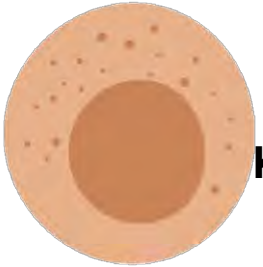
The Cells of the Immune System

Dendritic Cell

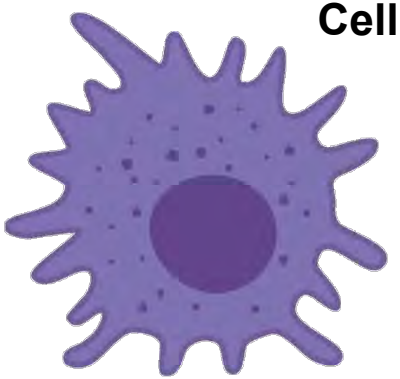
Monocyte



B Cell

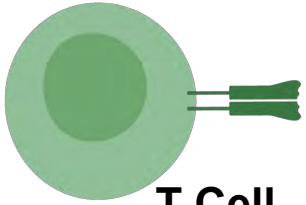


Natural Killer Cell



Macrophage

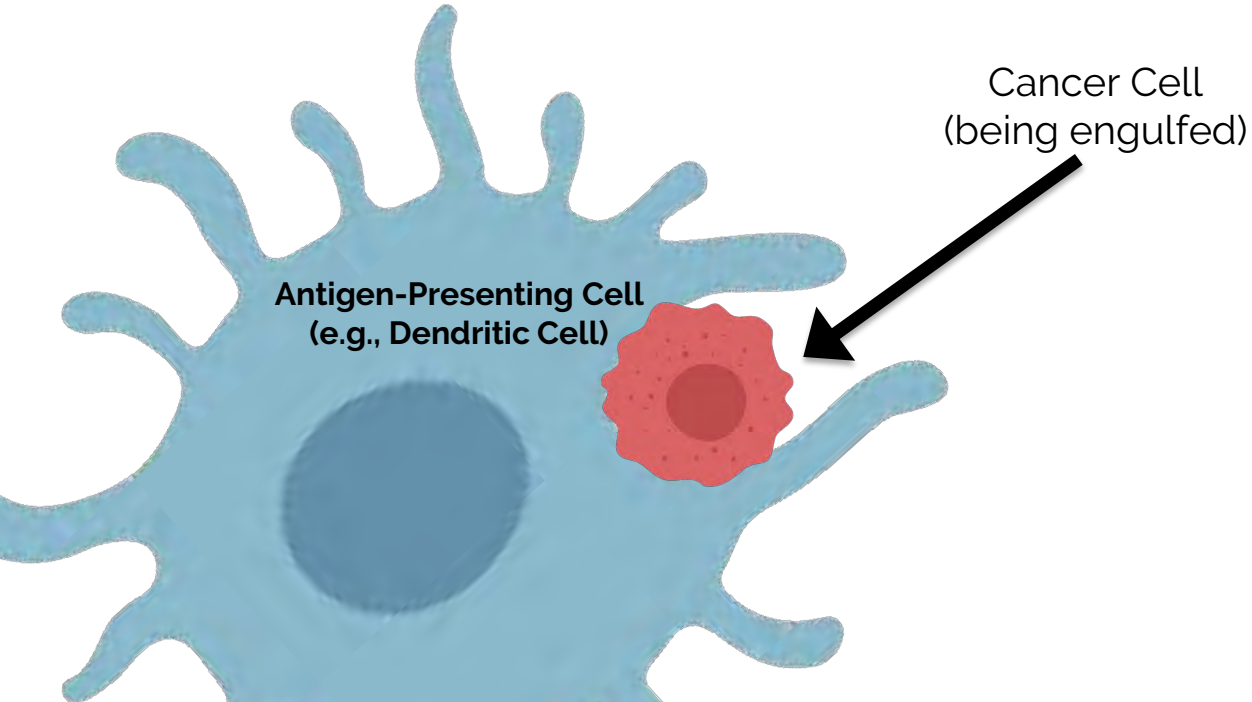
Neutrophil



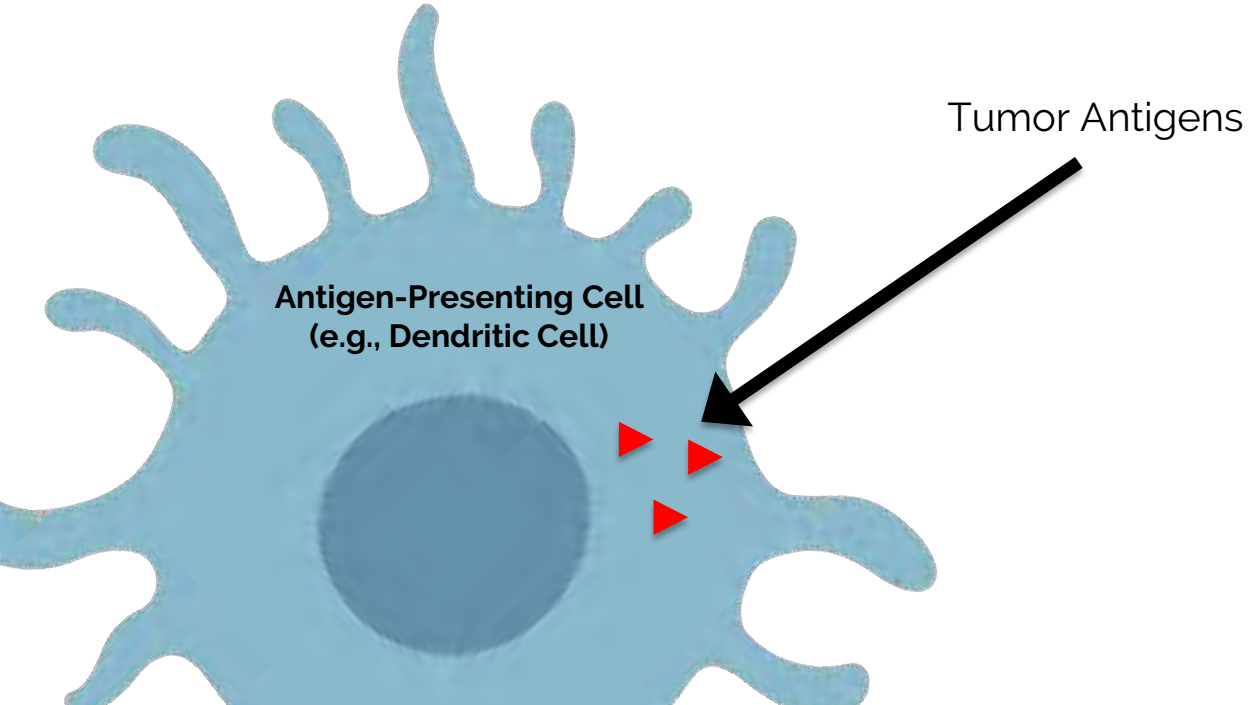
T Cell

CANCER RESEARCH INSTITUTE IMMUNOTHERAPY PATIENT SUMMIT

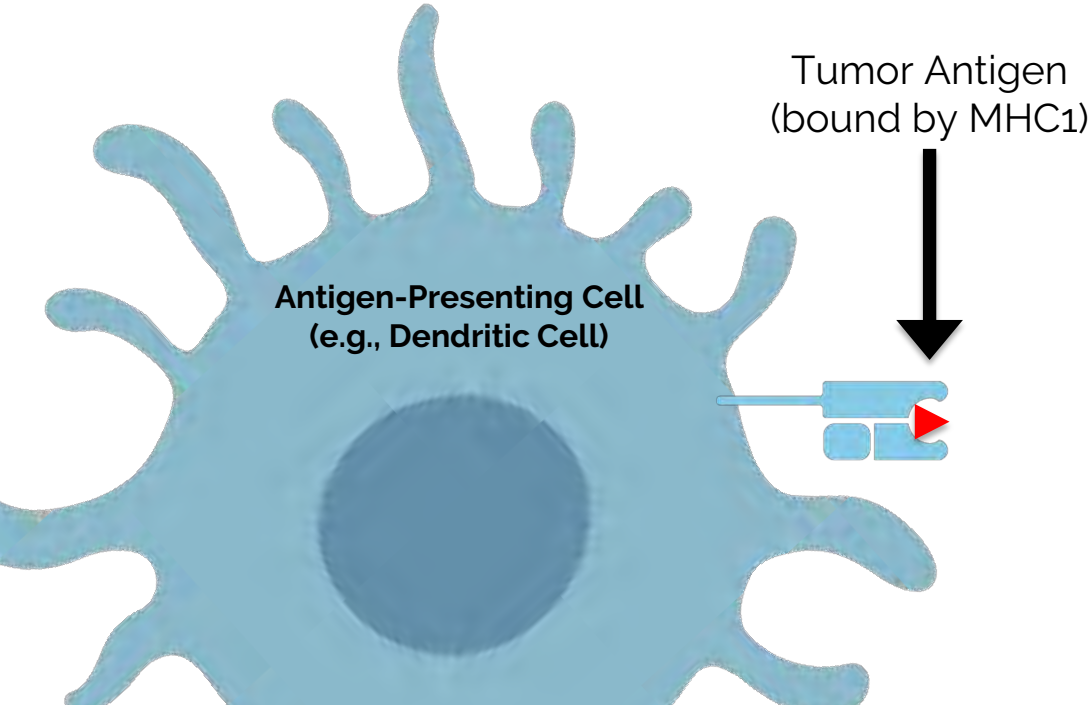
Adaptive Immune Responses Against Cancer



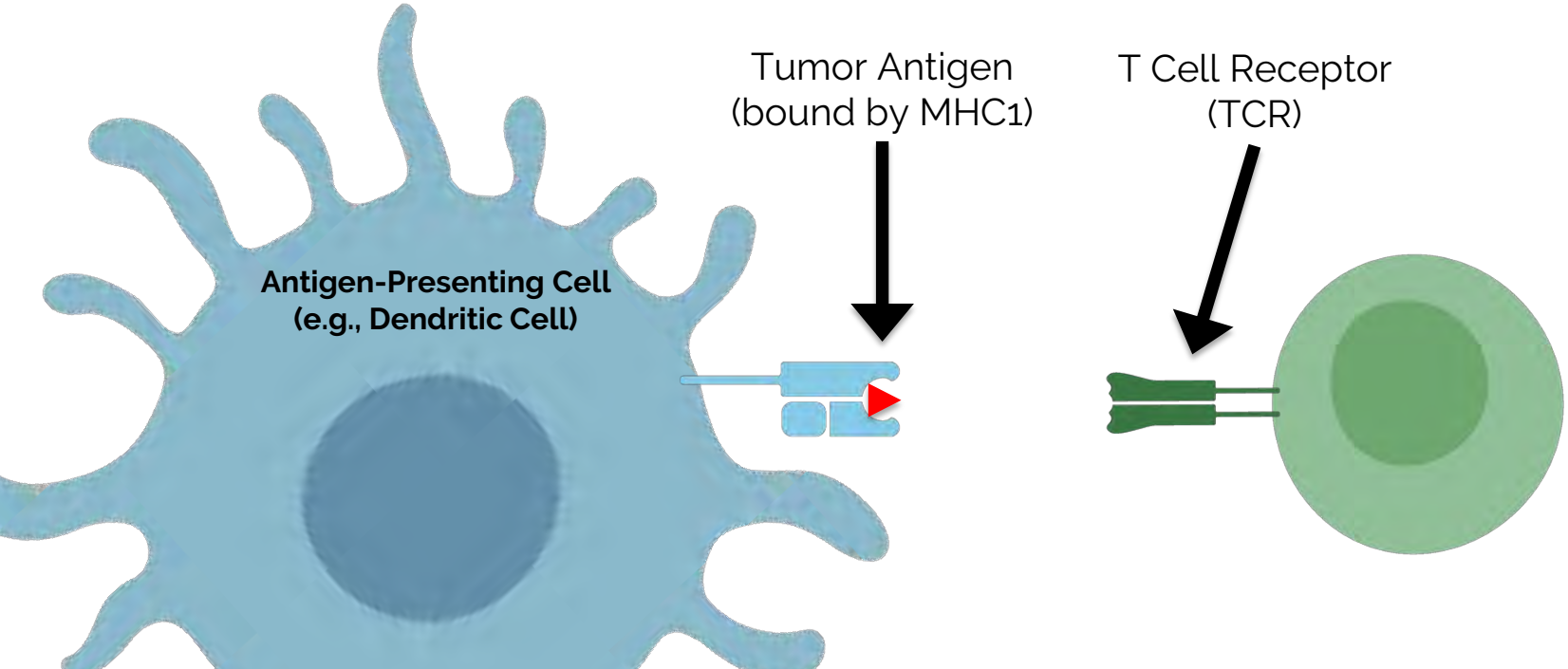
Adaptive Immune Responses Against Cancer



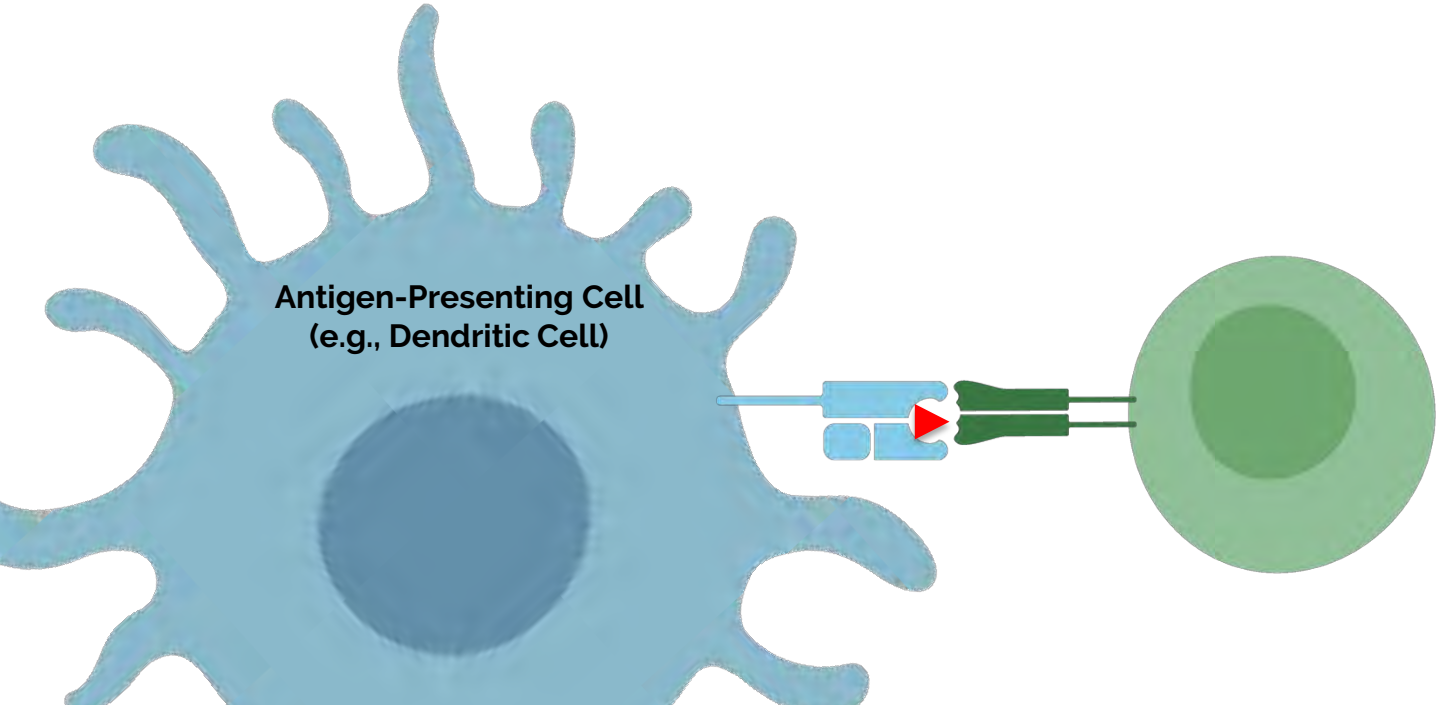
Adaptive Immune Responses Against Cancer



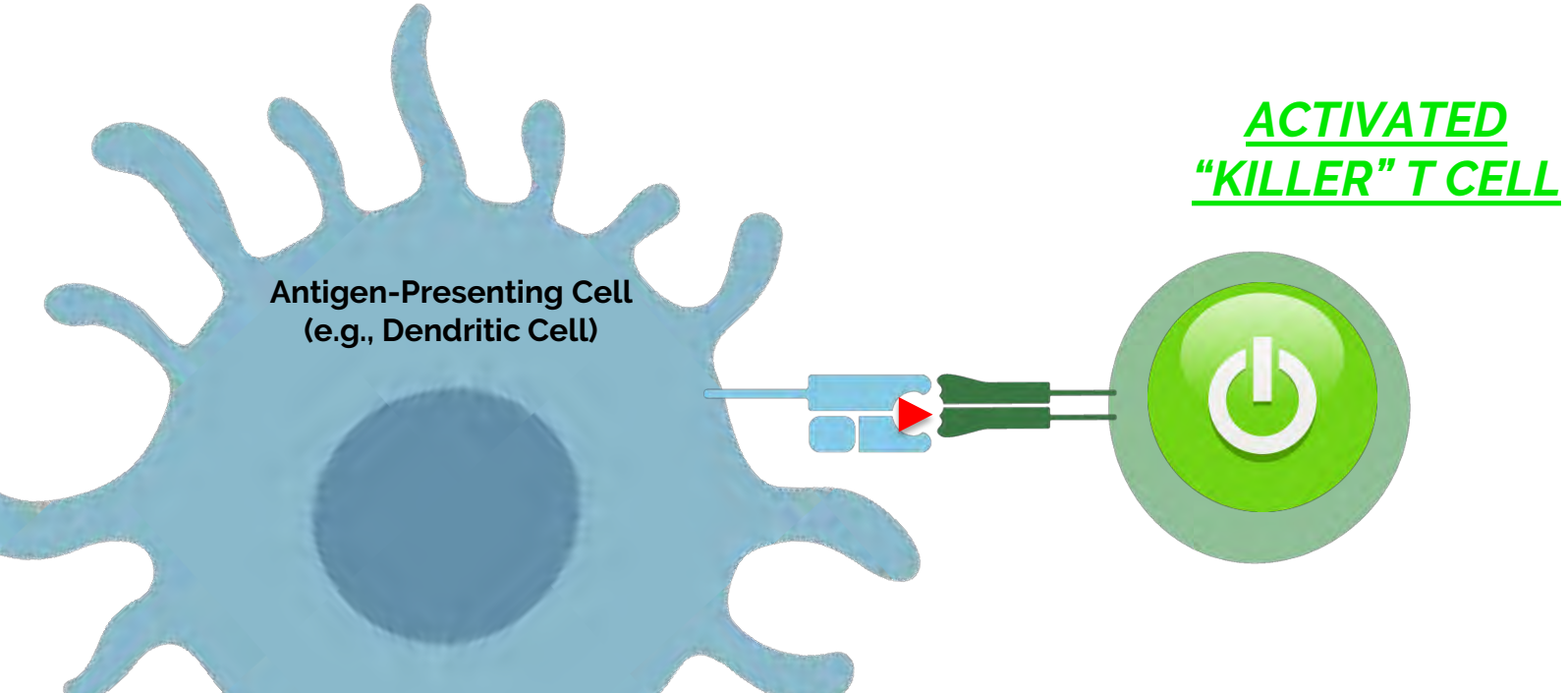
Adaptive Immune Responses Against Cancer



Adaptive Immune Responses Against Cancer

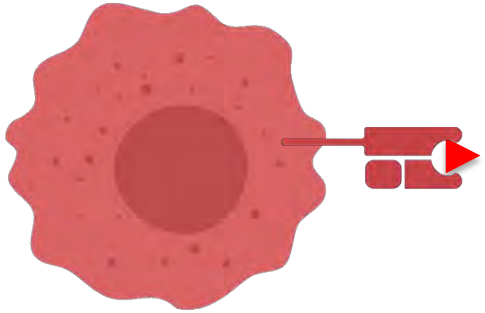


Adaptive Immune Responses Against Cancer

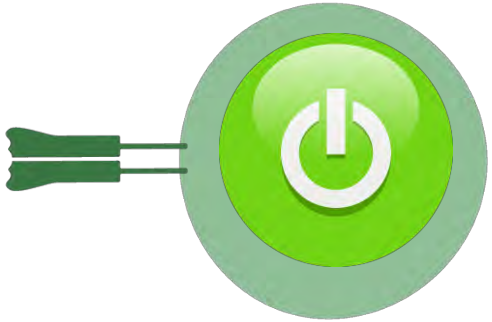


Adaptive Immune Responses Against Cancer

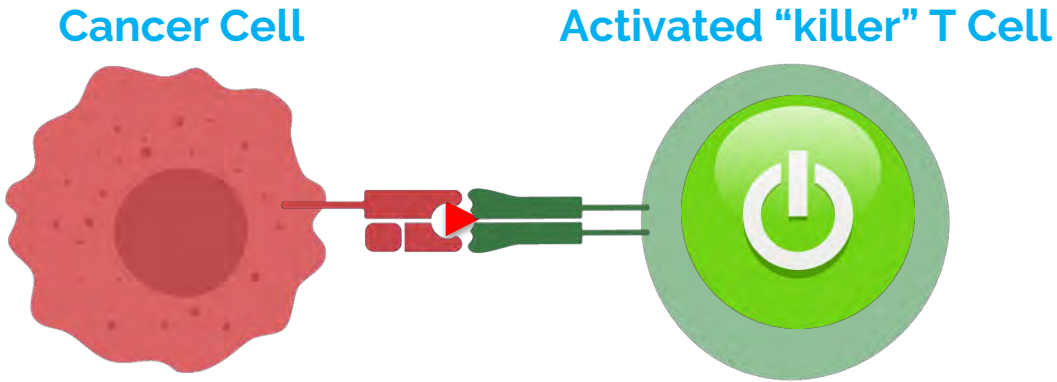
Cancer Cell



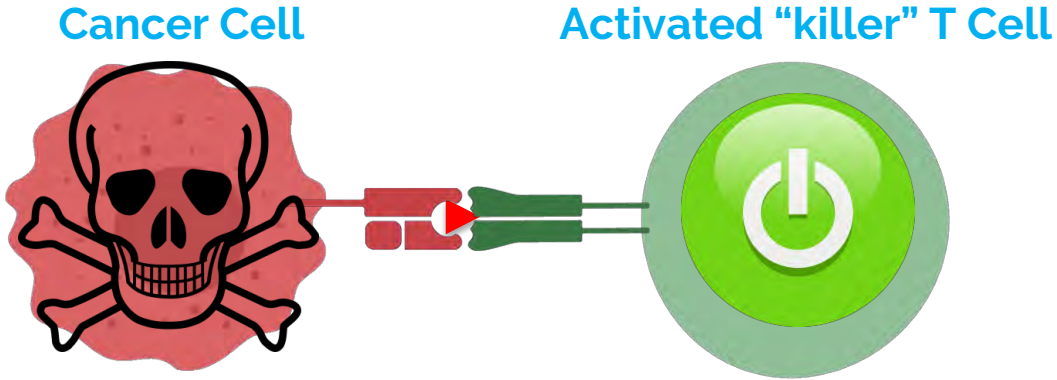
Activated “killer” T Cell



Adaptive Immune Responses Against Cancer

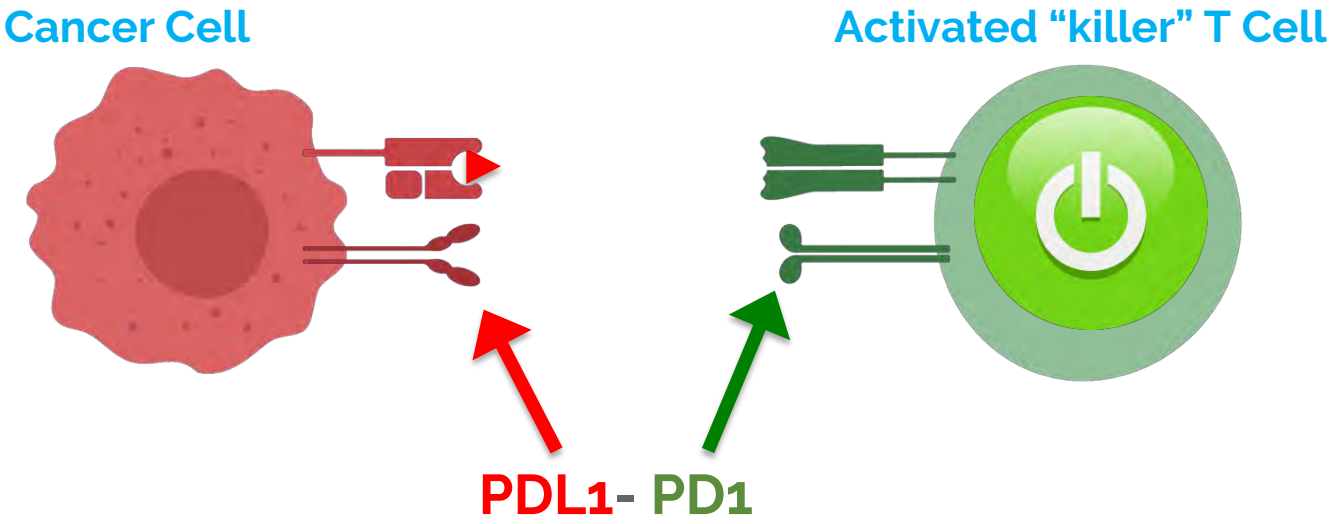


Adaptive Immune Responses Against Cancer

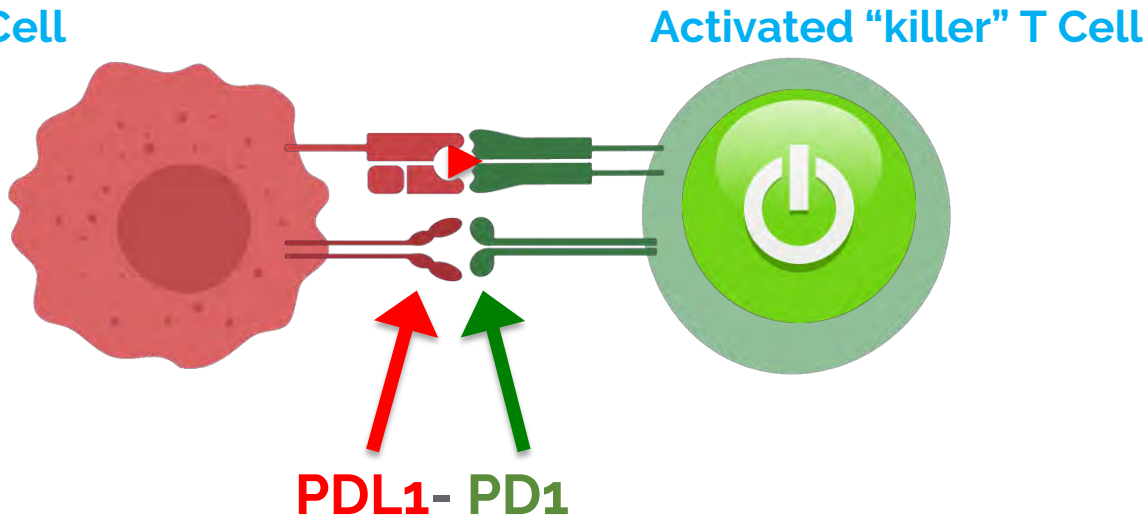


CANCER CELL ELIMINATED!

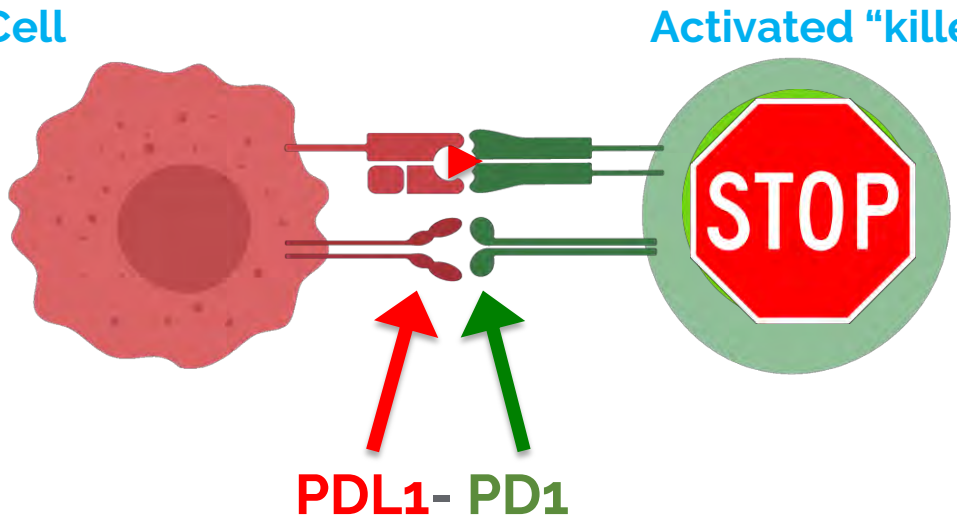
Immune Checkpoints Can Suppress Immune Responses



Immune Checkpoints Can Suppress Immune Responses



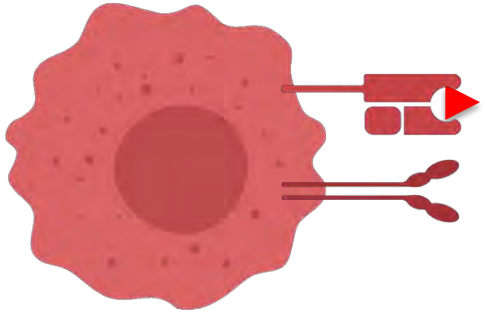
Immune Checkpoints Can Suppress Immune Responses



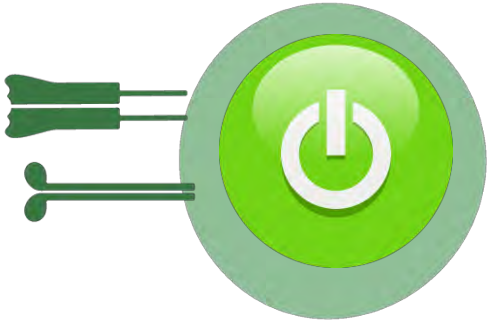
Normally, PDL1-PD1 leads to T cell “exhaustion”

Checkpoint Immunotherapy Can Promote Anti-Cancer Activity

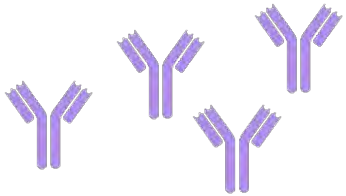
Cancer Cell



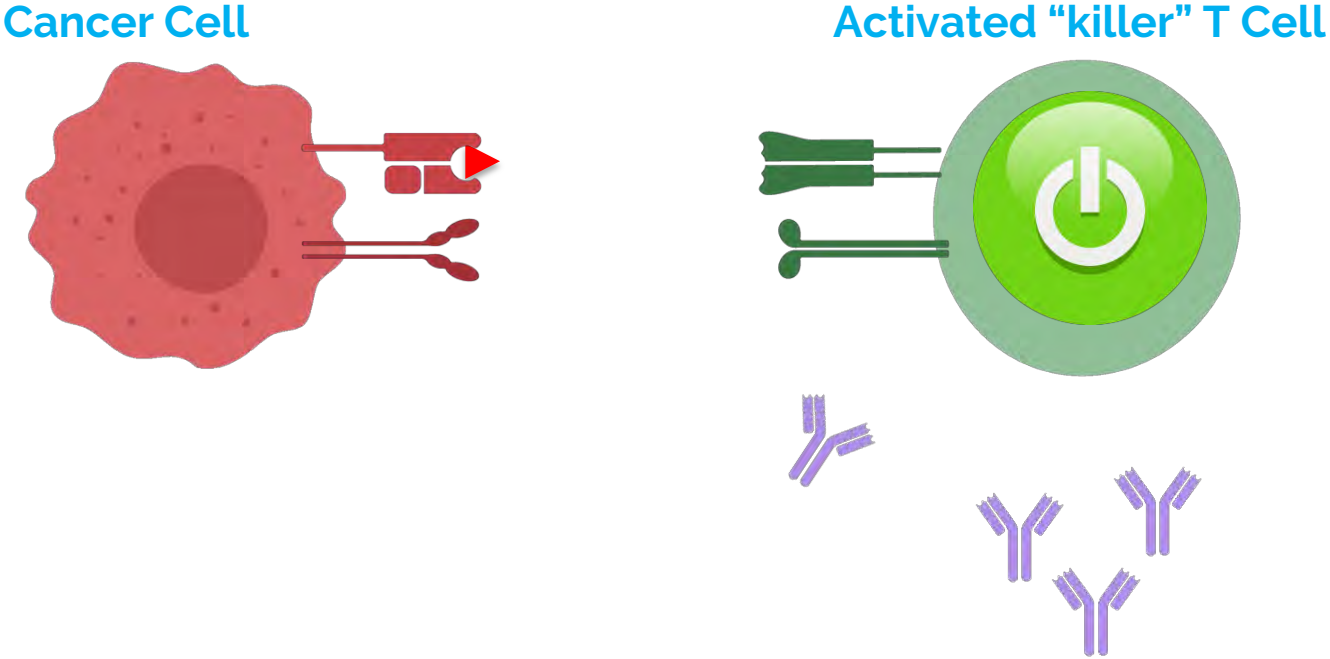
Activated “killer” T Cell



PD-1/PD-L1
Checkpoint Inhibitors

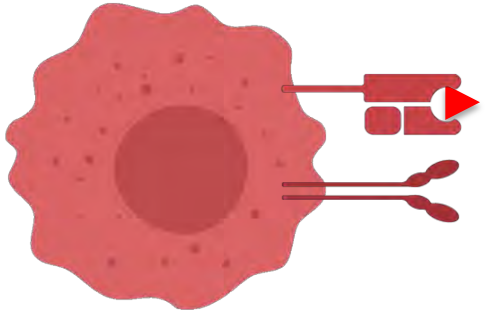


Checkpoint Immunotherapy Can Promote Anti-Cancer Activity



Checkpoint Immunotherapy Can Promote Anti-Cancer Activity

Cancer Cell



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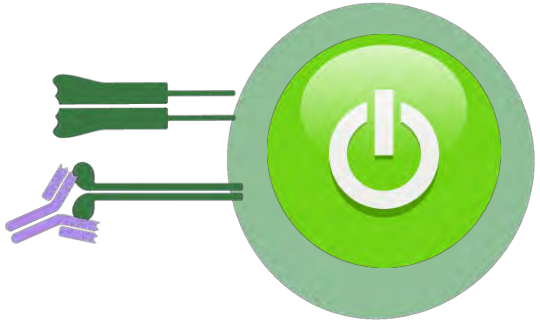
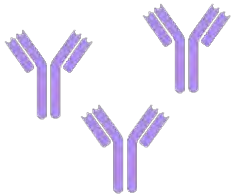
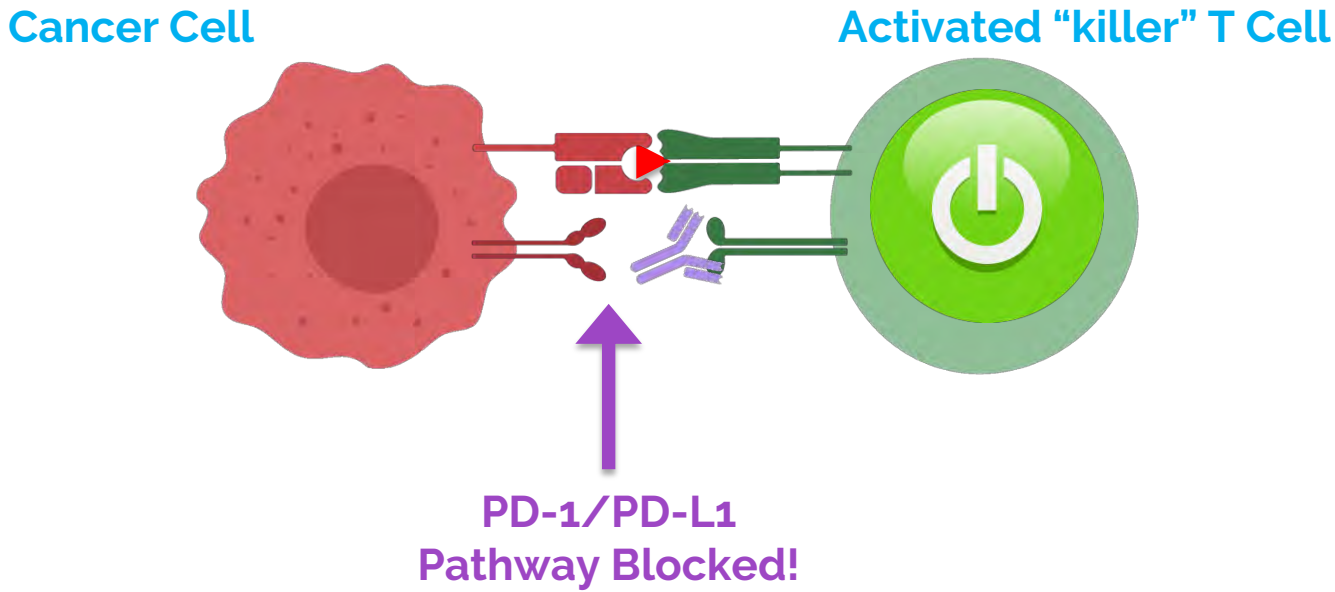




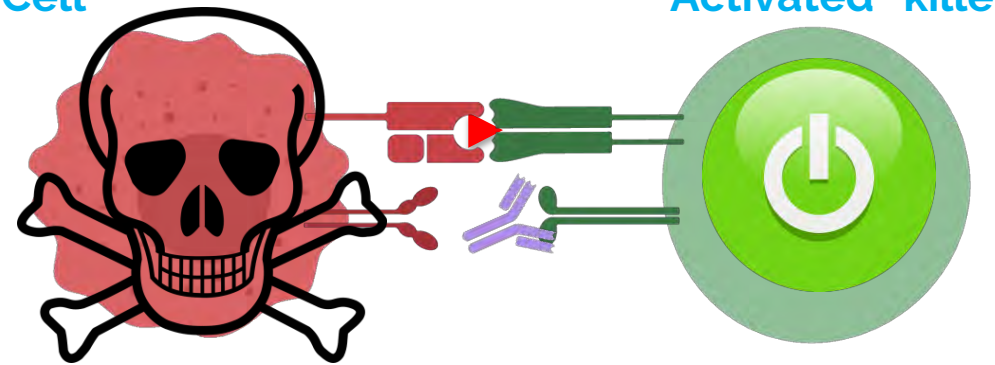
Checkpoint Immunotherapy Can Promote Anti-Cancer Activity



Checkpoint Immunotherapy Can Promote Anti-Cancer Activity

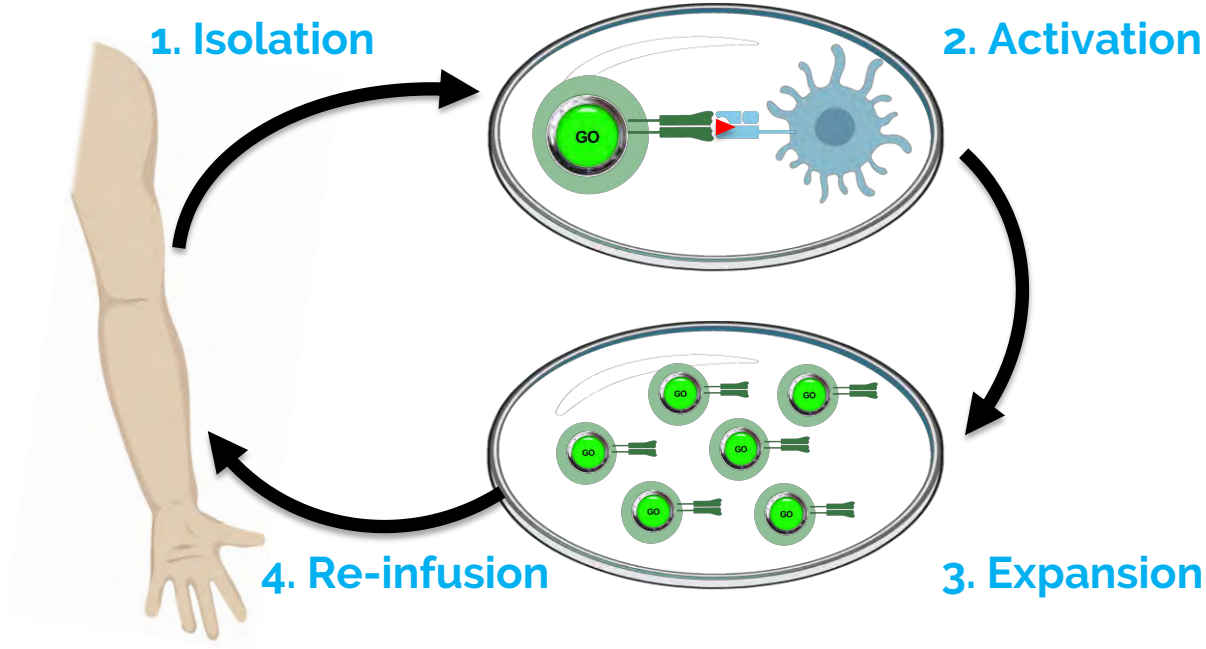
Cancer Cell

Activated “killer” T Cell

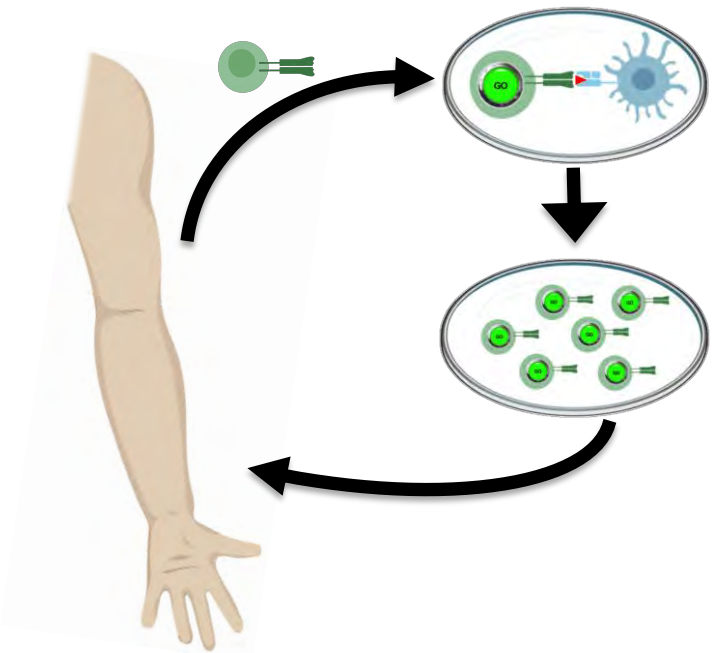


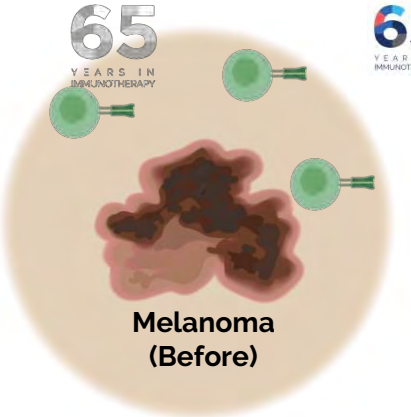
CANCER CELL ELIMINATED!

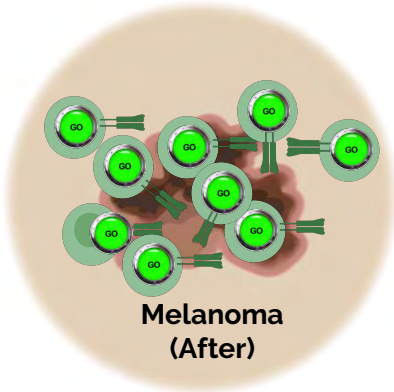
Adoptive T Cell Immunotherapy



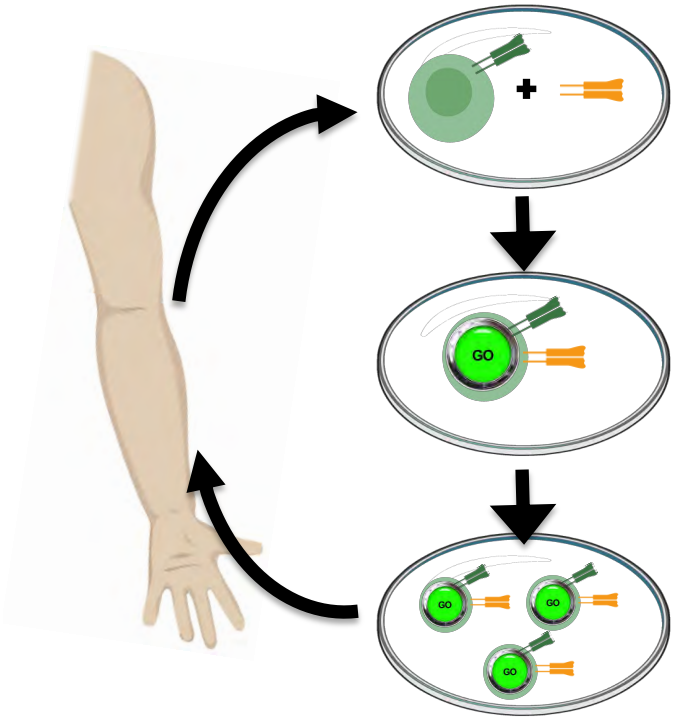
Adoptive T Cells In Action (Against Melanoma)





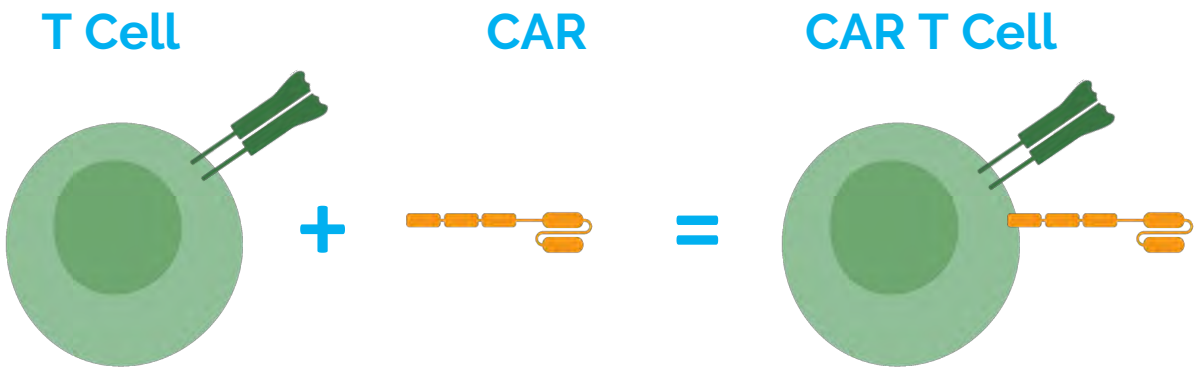


T Cell Receptor Engineering

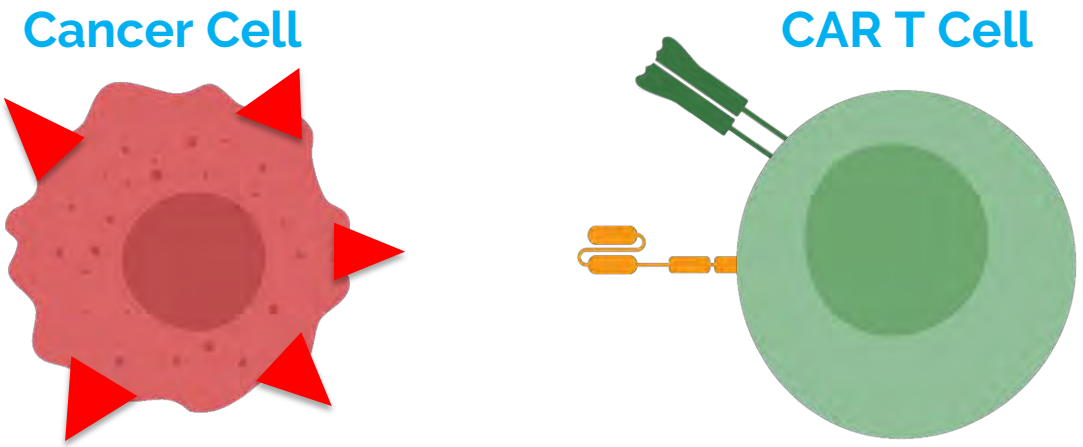


Equip T cells with new, cancer-targeting TCR

CAR T Cell Immunotherapy
(Chimeric Antigen Receptor)

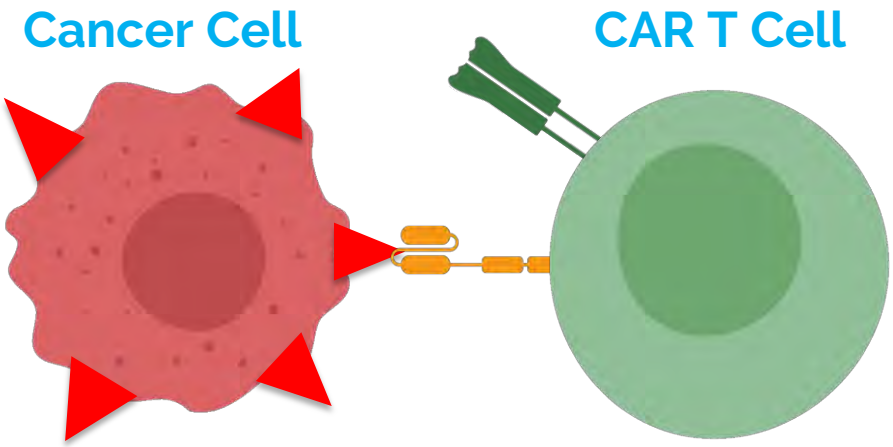


CAR T Cell Immunotherapy
(Chimeric Antigen Receptor)



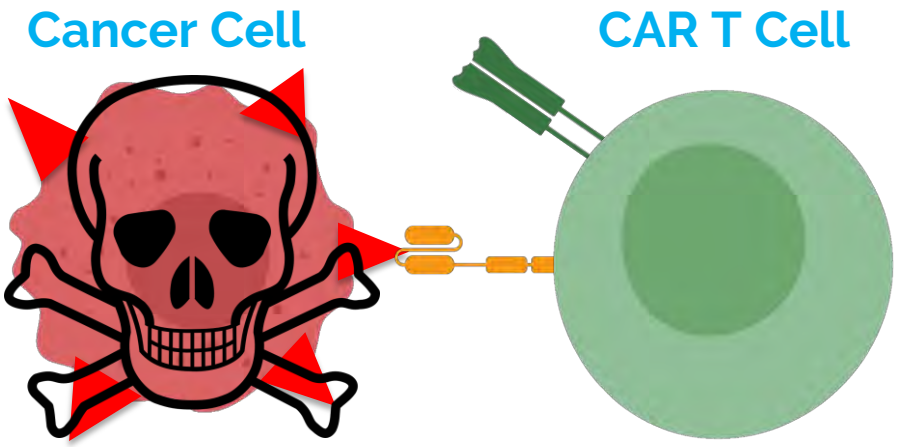
CARs enable MHC-independent targeting & killing!

CAR T Cell Immunotherapy
(Chimeric Antigen Receptor)



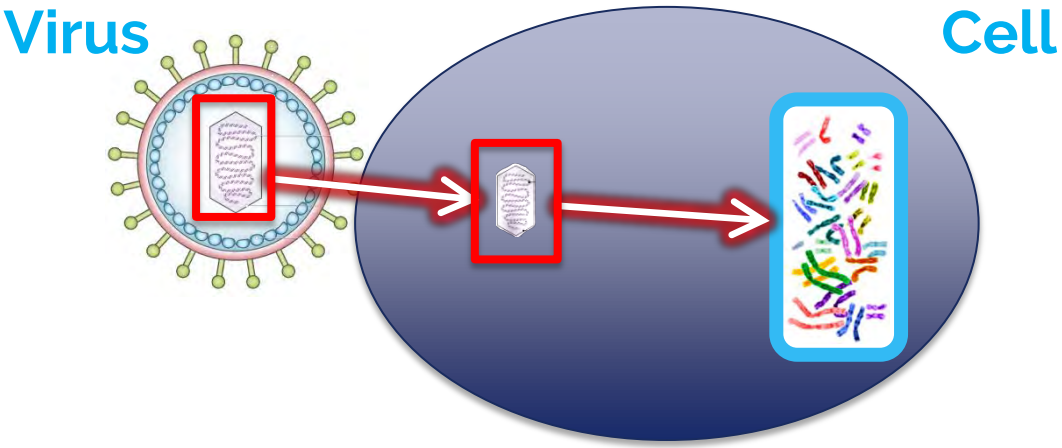
CARs enable MHC-independent targeting & killing!

CAR T Cell Immunotherapy
(Chimeric Antigen Receptor)



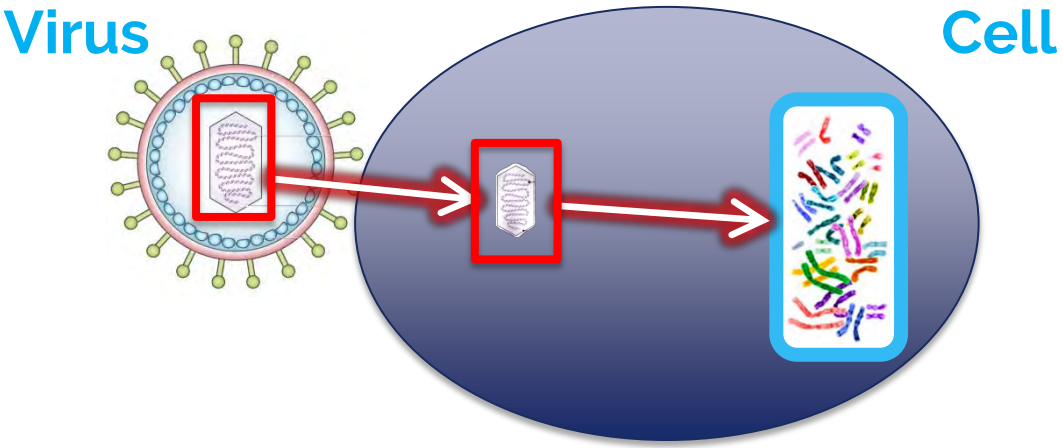
CARs enable MHC-independent targeting & killing!

Oncolytic Virus Immunotherapy



- Viruses can alter our cells' DNA, by inserting their own genetic material
- Impaired defenses make tumor cells more susceptible to infection

Oncolytic Virus Immunotherapy



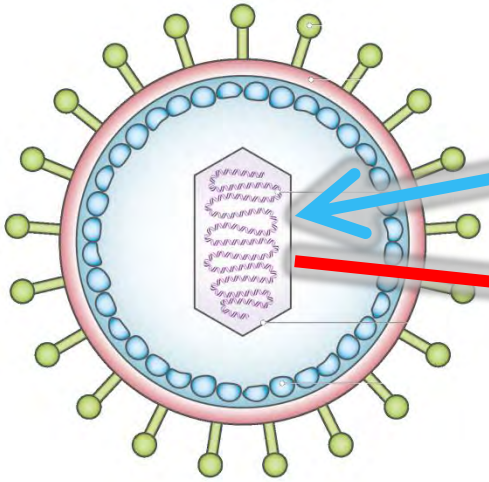
AFTER INJECTION:

1) Viruses cause tumor cells to “burst” & release antigens

2) Immune cells uptake & present tumor antigens

3) Stimulates adaptive, and potentially systemic, immune responses

Reprogramming Oncolytic Viruses To Enhance Anti-Tumor Activity

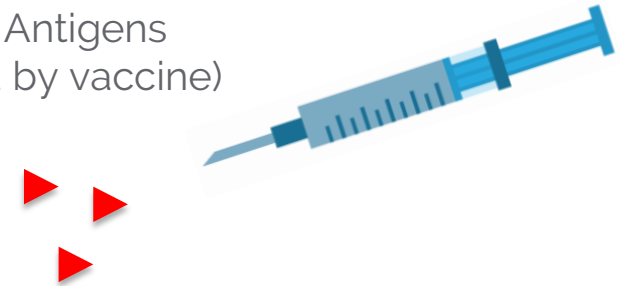


(+) INSERT
Immune-stimulating genes

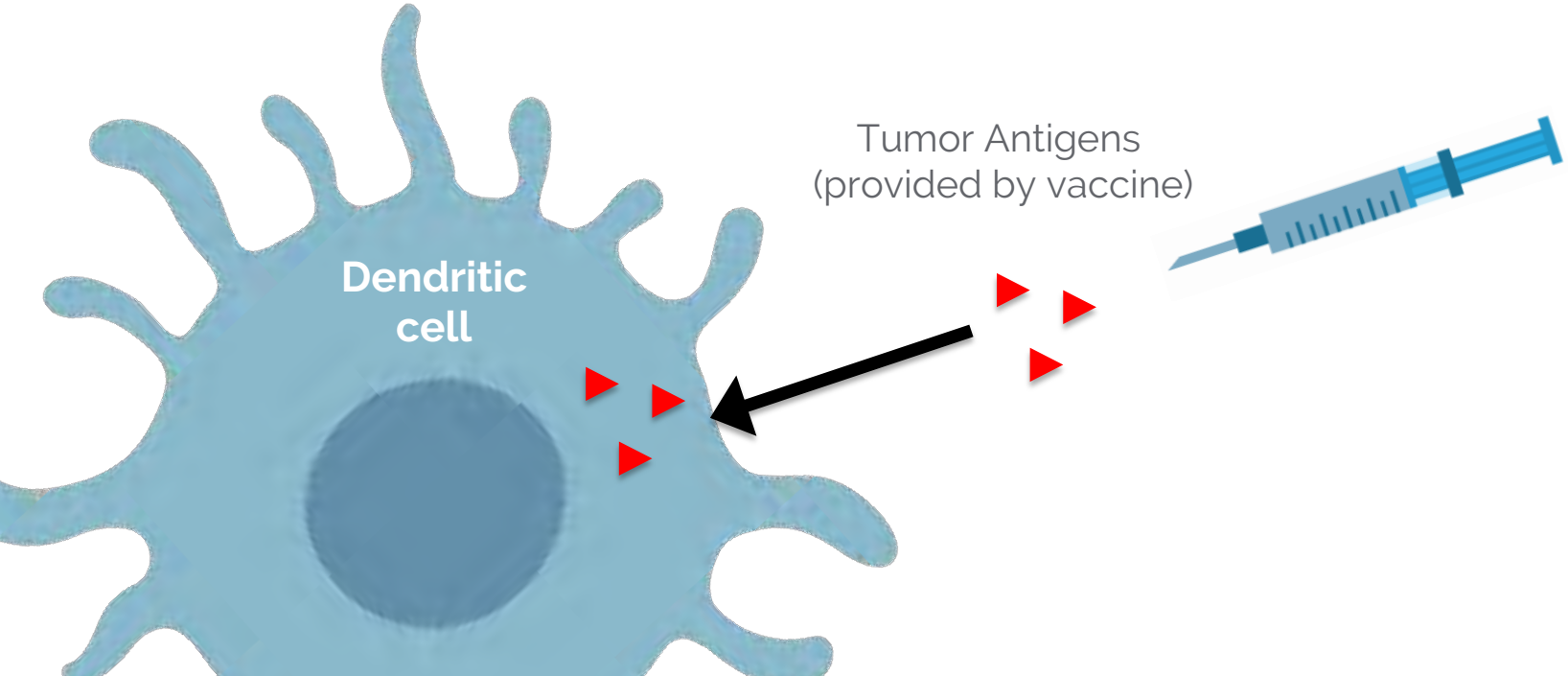
(—) REMOVE
Disease-causing genes (selective targeting of tumors)

Cancer Vaccines

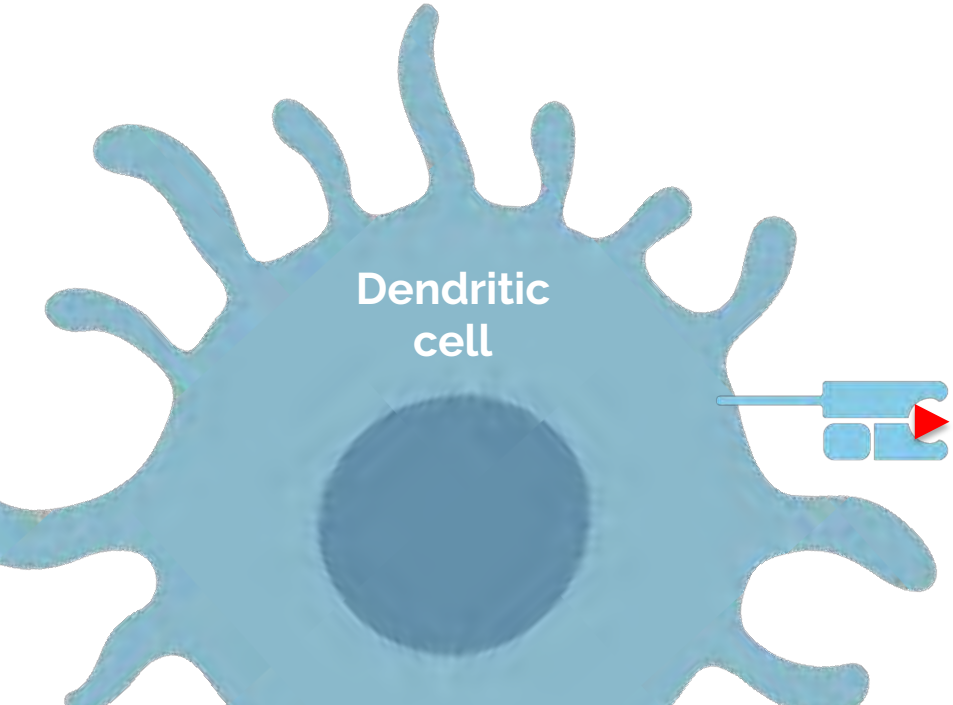
Tumor Antigens
(provided by vaccine)



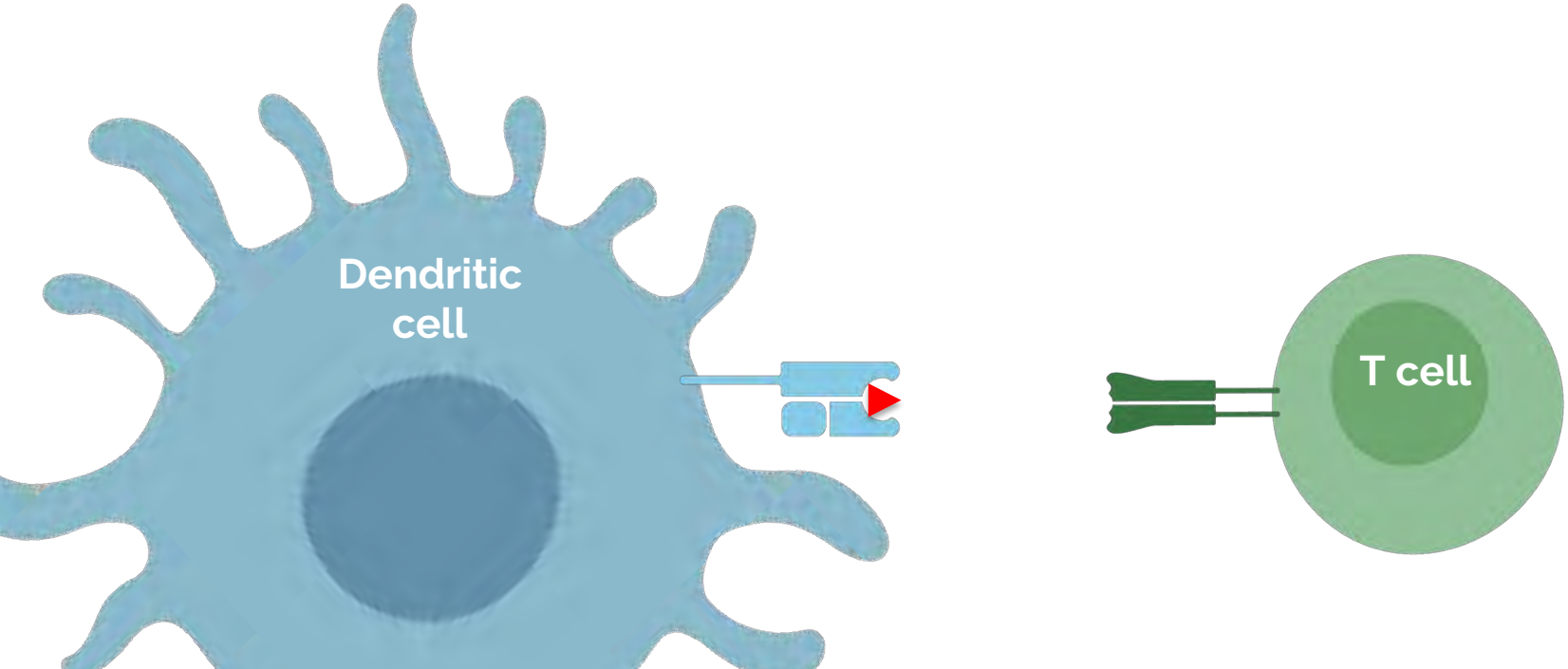
Cancer Vaccines



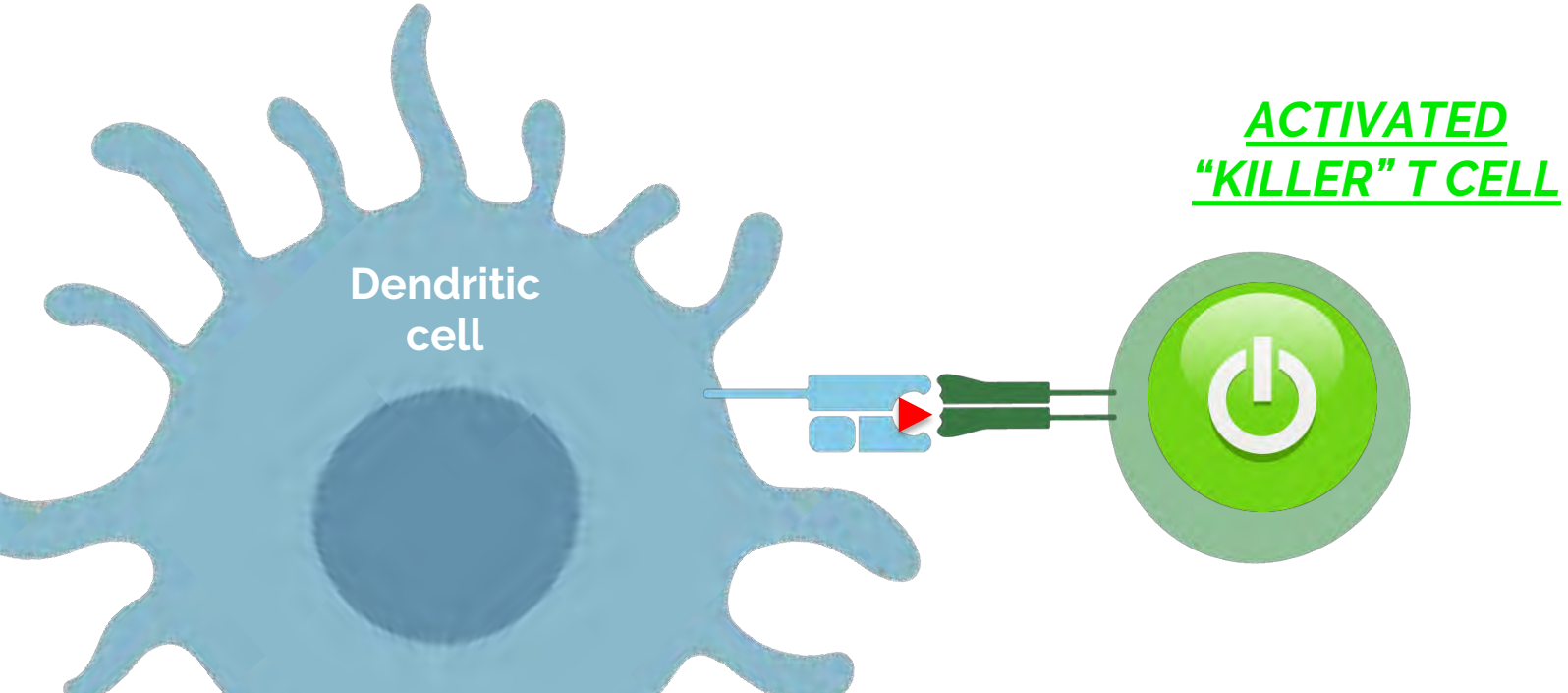
Cancer Vaccines



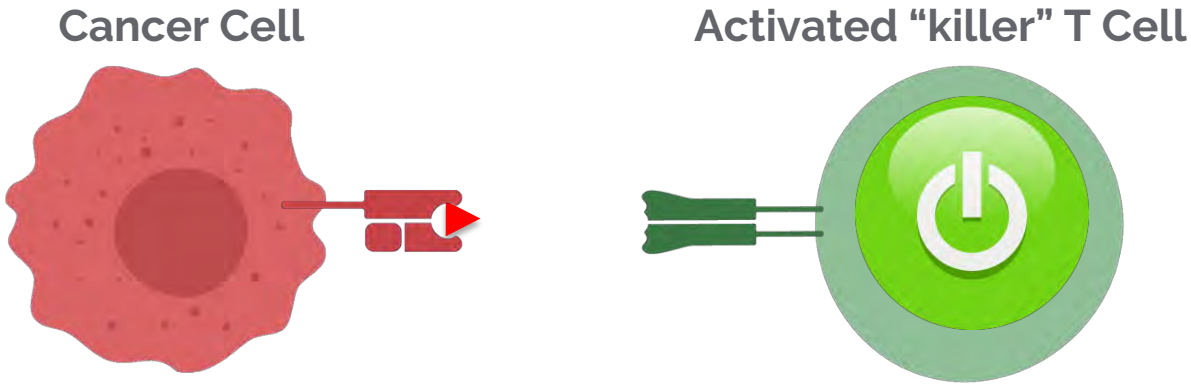
Cancer Vaccines



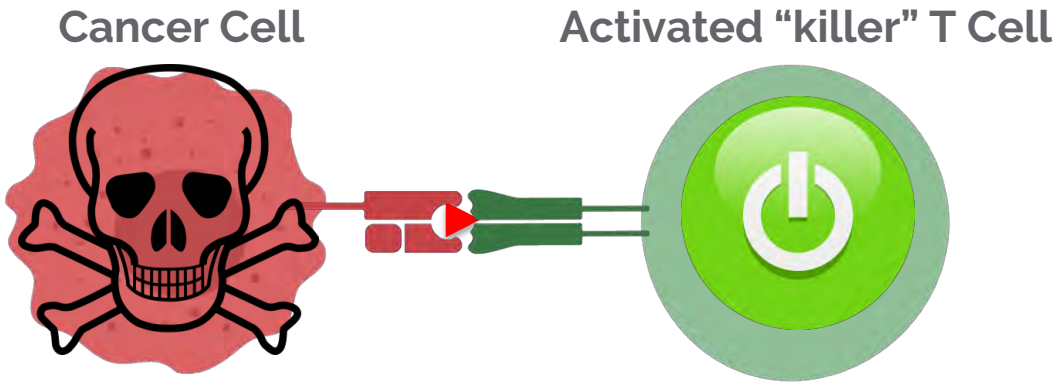
Cancer Vaccines



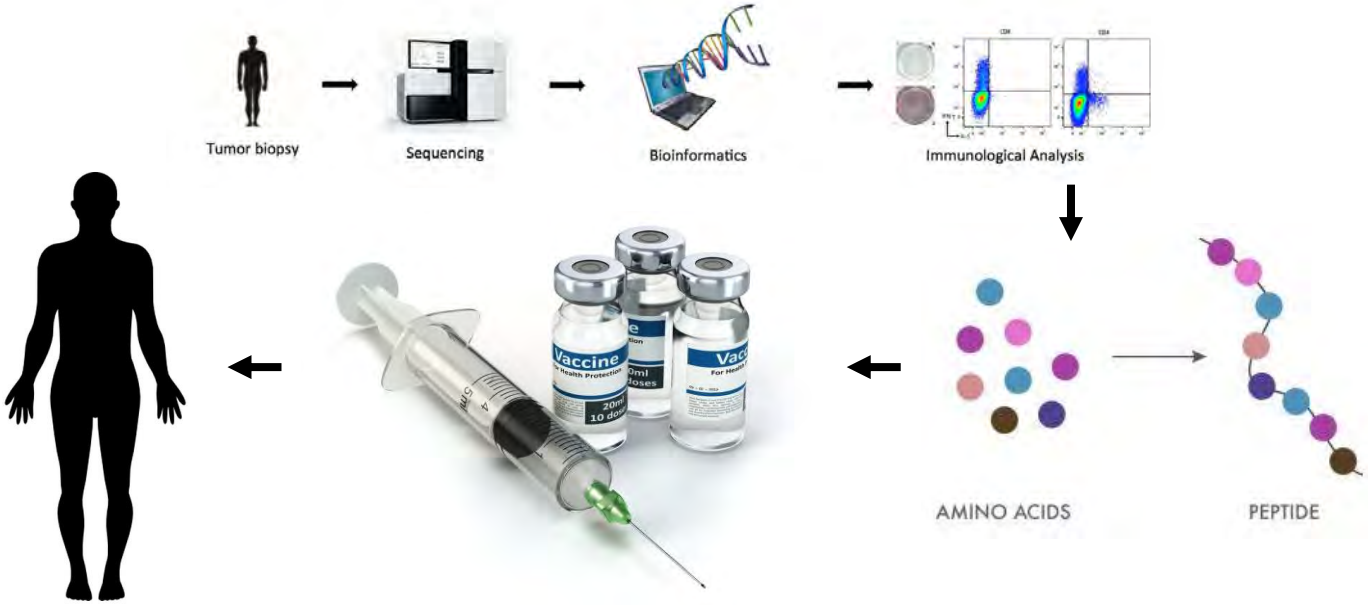
Vaccine-Induced Elimination of Cancer Cells



Vaccine-Induced Elimination of Cancer Cells



Personalized Neoantigen Vaccine Trial



Challenges in Cancer Immunotherapy

- Discovering and validating new biomarkers to help doctors predict which patients will respond to which immunotherapies

- Determining the best way to combine immunotherapies with each other as well other treatments to extend immunotherapy's benefits for more patients

- Learning how to decouple side effects of immunotherapy from benefit

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Panel Discussion

LATEST RESEARCH UPDATES

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Scientific Panel

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Moderator

Ezra Cohen, M.D.

Panel

Aaron M. Miller, M.D., Ph.D.
Gastrointestinal Cancers

Sandip P. Patel, M.D.
Lung Cancer

Rebecca A. Shatsky, M.D.
Breast Cancer

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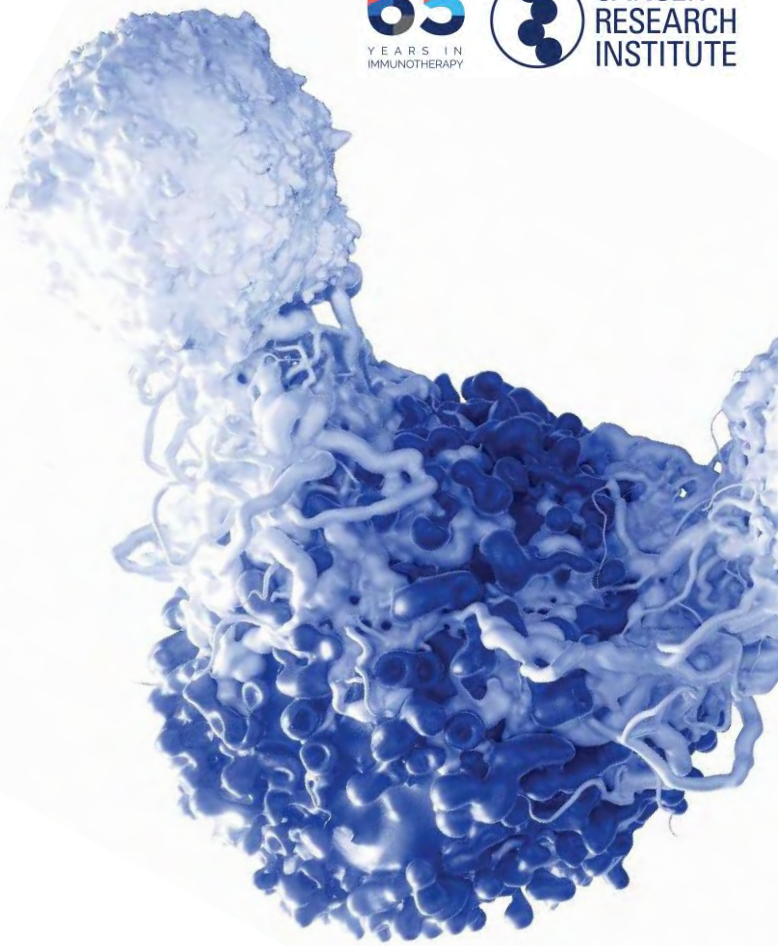

Kristin Kleinhofer

Surviving Acute Lymphoblastic Leukemia (ALL)

PATIENT PERSPECTIVE

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How did I get to Immunotherapy?

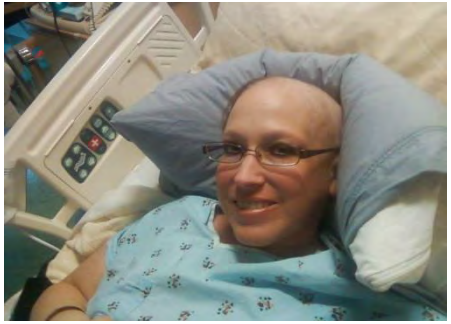
My Journey of HOPE

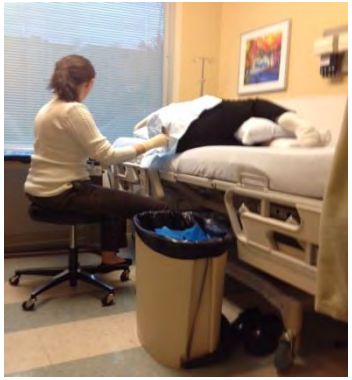
2010

August


I can be changed
by what
happens to me,
but I refuse
to be reduced by it.
Maya Angelou

2010 - 2012

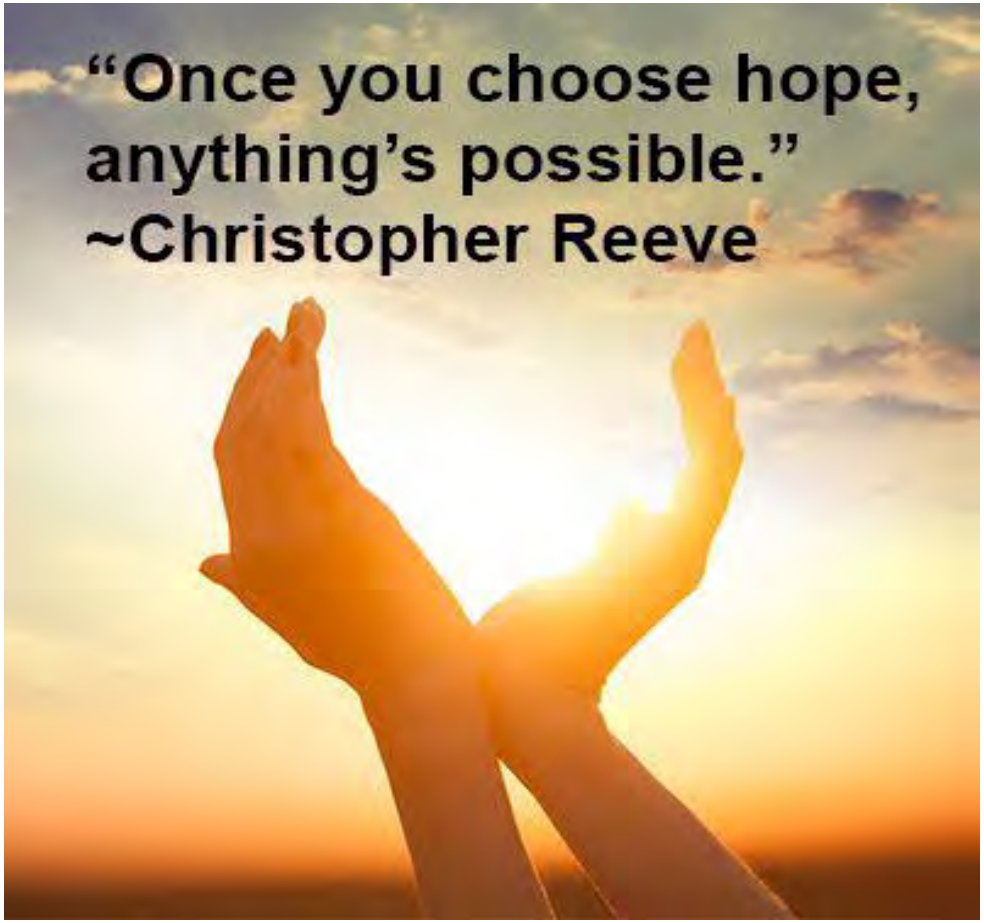




Enjoying Life.....

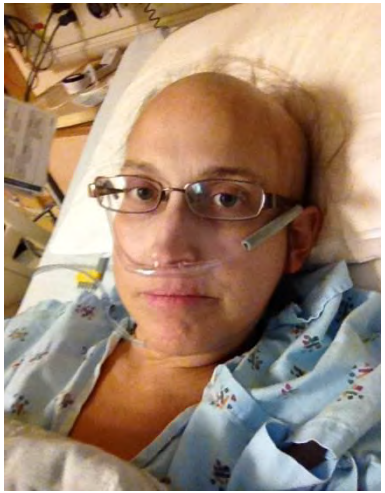
Now What to Do?

February & March 2014


“Once you choose hope, anything’s possible.”
~Christopher Reeve

Now What to Do?

April 2014



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Immunotherapy Eligibility

May 2014

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2014

September & October

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Protocol 2639

Phase I/II Study of Immunotherapy for advanced CD19+ CLL, ALL, and NHL with defined subsets of autologous T cells engineered to express a CD19 specific chimeric antigen receptor

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Receive

November 19, 2014

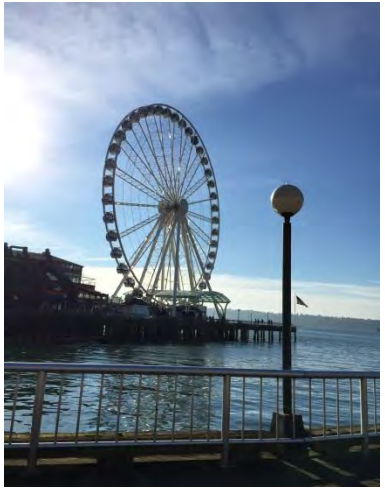
Immunotherapy Treatment

Reaction

- Spiked Fever
- Hospitalization
- Cytokine Release Syndrome
- Re-hospitalization

- High Fever
- Body Chills
- Muscle Aches
- Night Sweats
- Low Blood Pressure
- Mental Fogginess

Two Weeks Later……



Result

27 out of 29 (93%) A.L.L. patients Experience Sustained Remissions

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Protocol 2603

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Multi-center, Open-label Randomized Study of Single or Double Myeloablative Cord Blood Transplantation with or without infusion of off-the-shelf ex vivo expanded cyropreserved cord blood progenitor cells in patients with hematologic malignancies

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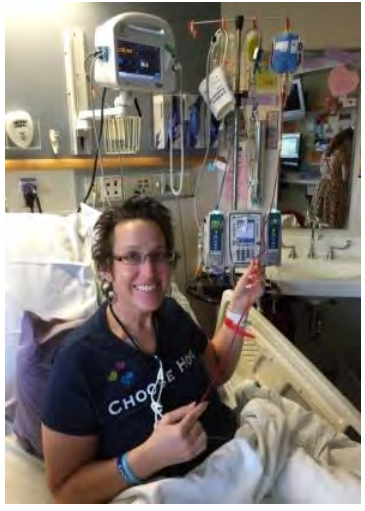
Receive

February 4, 2015

Transplant Journey Begins…



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Result

- Engraftment
- Naive Immune System
- Release after 100 days
- Return to CA

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Seattle Cancer Care Alliance
Fred Hutch · Seattle Children's · UW Medicine

UNIVERSITY OF WASHINGTON MEDICAL CENTER
UW Medicine

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Bucket List Continues...

Paying it Forward:

Patient Advocacy & Navigation

Takes a Village……..

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How to Make It Through the Dark Times?

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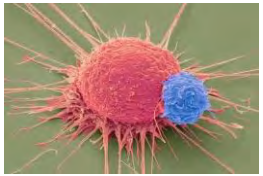
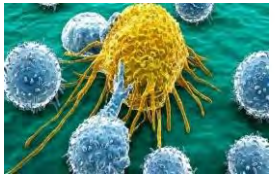
- Choose How We Want to Live Each Day
- Take It Day by Day, Live in the Present
- Gratitude for Life's Blessings
- Positive Attitude
- Acceptance
- Knowledge is Power
- Close Partnership w/ Medical Team
- Strong Support System. Stronger Together
- Inner Strength & Resilience to Push Forward
- Faith, Spiritual Life
- Humor
- Cancer Resources
- Choosing



Immunotherapy Treatments Offer HOPE



- Clinical Trials Are Where Revolutionary Breakthroughs Begin
- Standard Treatments Exhausted or No Longer Work
- Possible Gift of More Time
- Furthering Research to Help Future Cancer Patients
- Less Toxicity & More Targeted Therapy
- Changing the Cancer Treatment Landscape
- Profound Impact on What Cancer Care Will Mean in Coming Years
- Exciting Time as More Discoveries Are Made and Perfected

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IMAGINE the Day.....

Cancer will not be a Word we are afraid of. No more harsh side effects, no more relapses, just our body's immune system being led to harness its wisdom to conquer Cancer through Immunotherapy.

Just Imagine.

"*Once you Choose Hope, Anything is Possible*."

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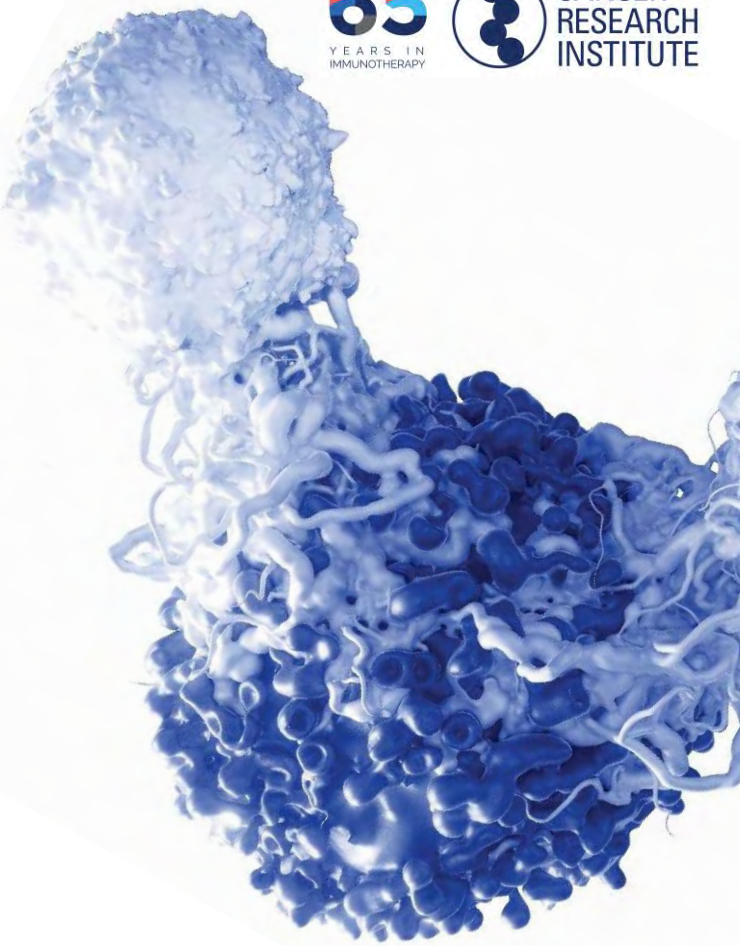
Lunch and Networking

Level 1 | Room 141/143/145



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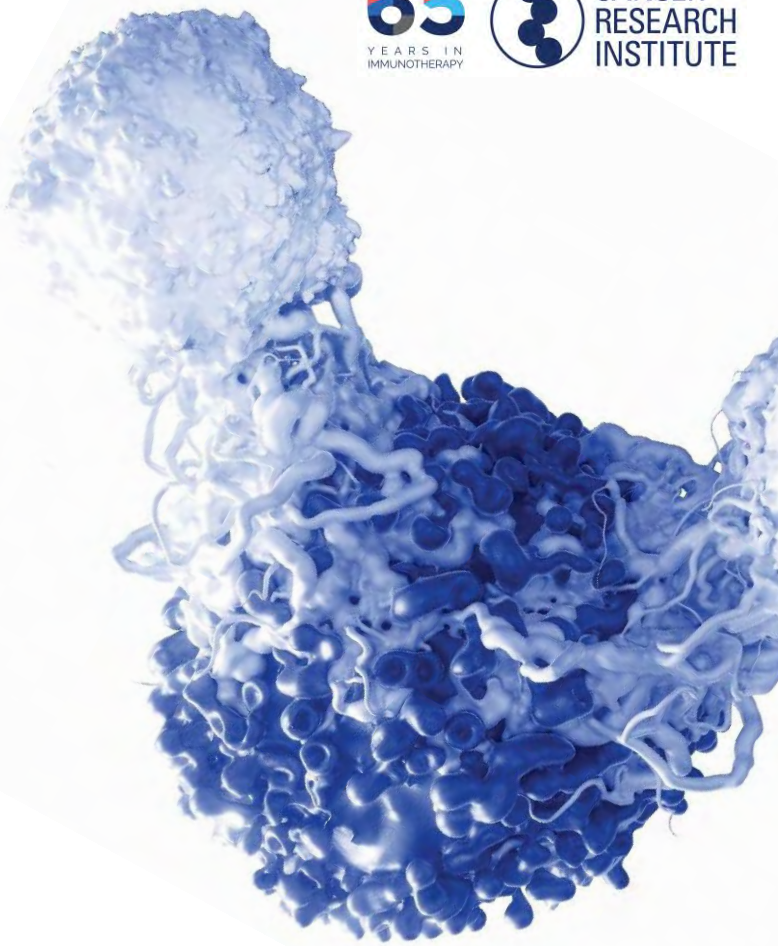

Brian Brewer

Cancer Research Institute

LEARN ABOUT CLINICAL TRIALS

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What Are Clinical Trials?

- Research studies that involve people
- Designed to answer specific questions about new and existing treatments
- Aim to improve treatments and the quality of life for people with disease

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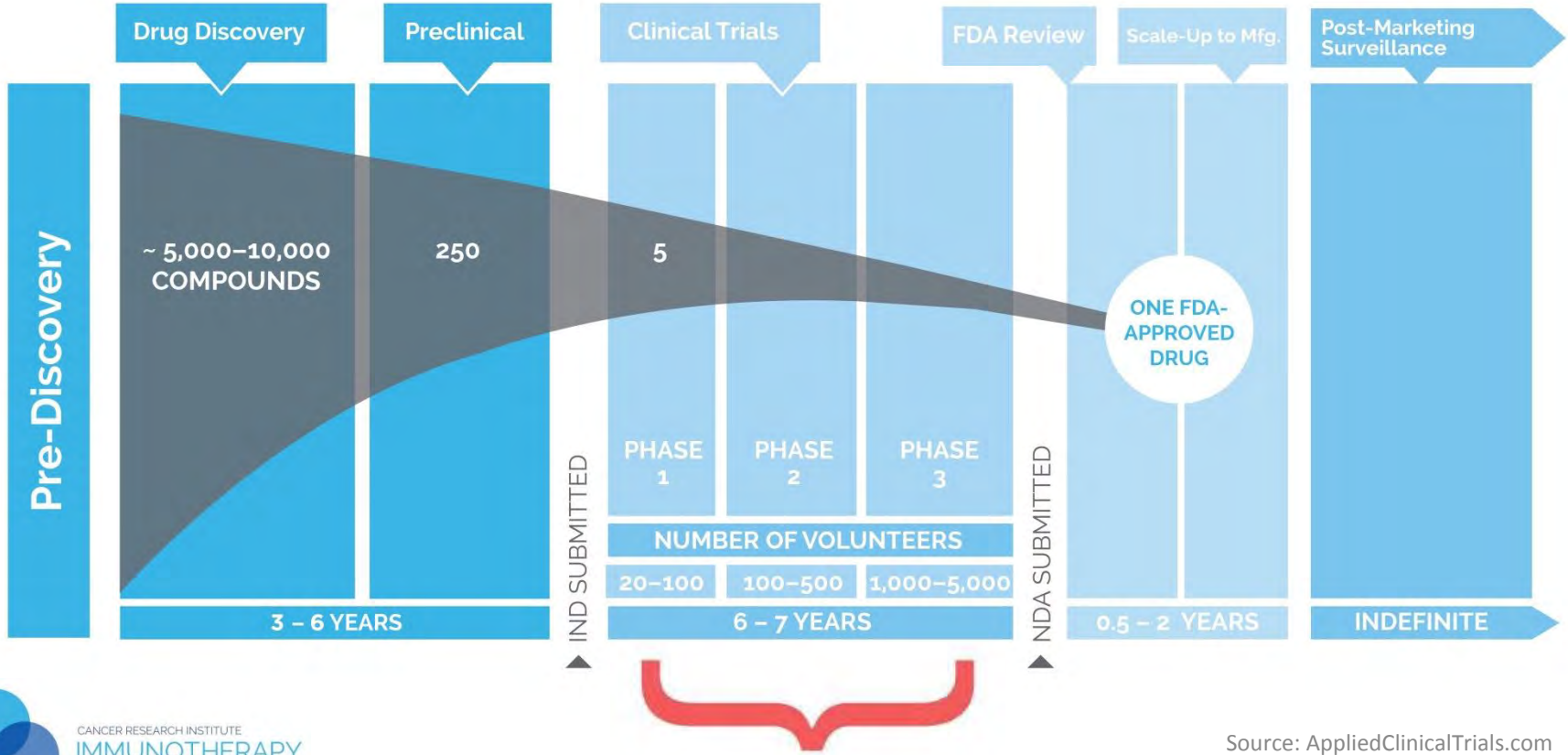
Getting from Discovery to Approval



Source: AppliedClinicalTrials.com

What Are Clinical Trial Phases?

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Phase 1

Is the treatment safe?

Purpose:

- First study in humans
- Find best dose, delivery method, and schedule
- Monitor for side effects
- Determine safety

Number of people: 20-100

Phase 2

Does it work?

Purpose:

- Look for effect on specific type(s) of cancer
- Continue monitoring for side effects and safety

Number of people: 100-500

Phase 3

Does it work better?

Purpose:

- Compare new treatment (or new use of a treatment) with current standard treatment
- Determine risk vs. benefit

Number of people: 1,000-5k+

Patient Resource, "Understanding Clinical Trials: A Guide for Patients and Their Families"

Pros and Cons of Clinical Trials

Potential Advantages	Potential Disadvantages
Access to best possible care	Unknown side effects or risks
Receiving new drugs before they're widely available	Unknown benefits—drugs may not work as intended
Close monitoring by medical team	Not all patients may benefit
Chance to play active role in healthcare and research	Frequent tests and clinic visits
Help future generations	Possible need to travel to trial sites

Patient Resource, "Understanding Clinical Trials: A Guide for Patients and Their Families"

Questions to Ask Before Volunteering

- Why is this trial being done?
- Why is it believed that the treatment being studied may be better than the standard treatment?
- What are my other options (standard treatments, other trials)?
- How did patients do in any previous studies of this treatment?
- How will the doctor know if treatment is working?
- How long will the trial last?

Patient Resource, "Understanding Clinical Trials: A Guide for Patients and Their Families"

Questions to Ask Before Volunteering

- Can I continue to receive this treatment after the trial ends?
- What kinds of procedures or tests are involved?
- What impact with the trial have on my daily life?
- Will I have to travel for treatment? Will I be compensated?
- How often will I need to travel to receive treatment?
- Will I be hospitalized as part of the trial?
- What costs (if any) will be my responsibility to pay?

Patient Resource, "Understanding Clinical Trials: A Guide for Patients and Their Families"

Getting into a Clinical Trial Isn't Always a Given

Trials are designed to ask specific questions, and must adhere strictly to entry criteria to ensure data is accurate and meaningful.

This also helps ensure patients who could be made worse by treatment are not exposed to the risk.

Common criteria include:

- **cancer type or stage**
- **treatment history**
- **genetic factors**
- **age**
- **medical history**
- **current health status**

Clinical Trials: Myth versus Fact

I might only get placebo
("sugar pill") instead of treatment.

Placebos are rarely used and never given
in the absence of some form of treatment.

Patient Resource, "Understanding Clinical Trials: A Guide for Patients and Their Families"

Clinical Trials: Myth versus Fact

Trials are only for people who have run out of treatment options (a “last resort”).

Clinical trials are designed for people with cancer of all types and stages.

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Patient Resource, “Understanding Clinical Trials: A Guide for Patients and Their Families”

Clinical Trials: Myth versus Fact

I need to travel to a large hospital or cancer center to participate in a clinical trial.

Trials take place at local hospitals, cancer centers, and doctors' offices in all parts of the country, in both urban and rural areas.

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Clinical Trials: Myth versus Fact

My health insurance doesn't cover the cost of care in a clinical trial.

Doctor visits, hospital stays, and certain testing procedures may be covered by insurance. Research costs are typically covered by the trial sponsor.

Patient Resource, "Understanding Clinical Trials: A Guide for Patients and Their Families"

Clinical Trials: Myth versus Fact

Signing a consent form “locks” me into staying in a trial.

Fact: You are free to change your mind for any reason about participating in a trial anytime before or during a trial.

Clinical Trials: Myth versus Fact

I will be made to feel like a "guinea pig" experiment.

Fact: The overwhelming majority of trial participants say they were treated with dignity and respect, and report having had a positive experience in a trial.

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Clinical Trials: Myth versus Fact

Clinical trials aren't safe.

Fact: Safeguards including an Institutional Review Board, Data and Safety Monitoring Board, and an ongoing informed consent process ensure patients' rights and safety are protected.

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A Word About Informed Consent

Informed consent = having all the facts before and during a trial

- Study purpose
- Length of time of the study
- Predictable risks
- Possible benefits
- Expectations
- Patient's rights

- Treatment alternatives
- Patient health monitoring
- Safeguards in place
- How to withdraw from study

Be bold in asking for details.
It's YOUR treatment plan.

How Can I Find a Clinical Trial?

- Ask your doctor
- Ask another doctor if necessary…
- Contact a patient advocacy organization
  - Seek assistance from a clinical trial navigator, if offered
  - CRI Clinical Trial Finder: 1 (855) 216-0127
- Search online
  - https://www.cancerresearch.org/patients/clinical-trials
  - https://clinicaltrials.gov/

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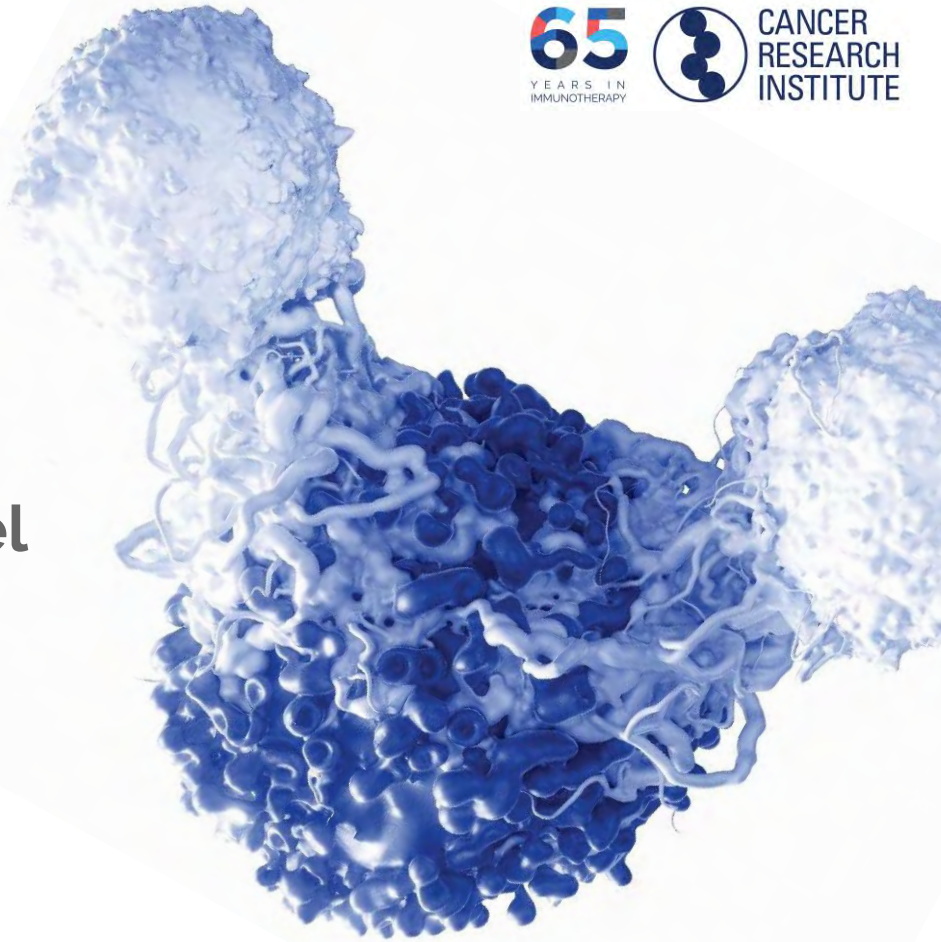

Panel Discussion

Immunotherapy Patient Panel

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Patient Panel

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Moderator	Panel
Brian Brewer	**Dan Engel** Melanoma
	Kristen Kleinhofer Acute Lymphoblastic Leukemia (ALL)
	Rikki Rockett Oral Cancer
	Rebecca S. Breast Cancer

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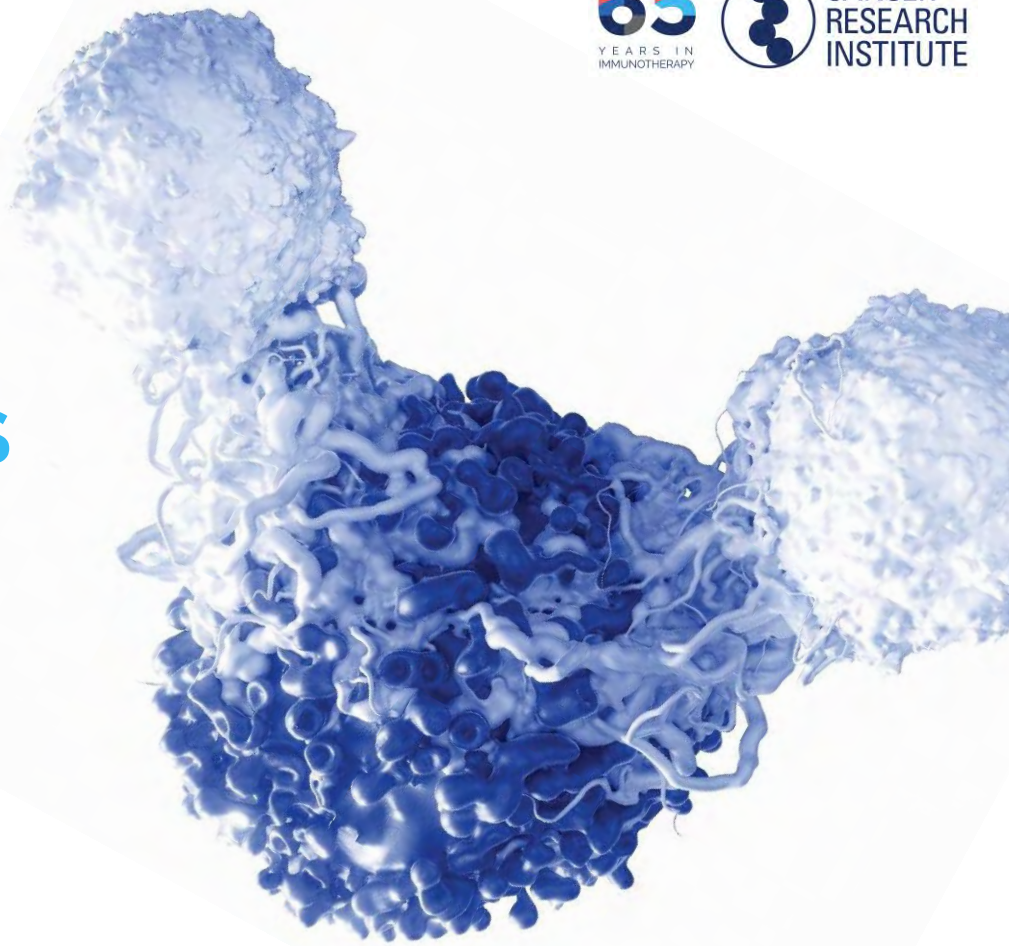
BREAKOUT SESSIONS



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Breakout Session Rooms

General Immunotherapy Ezra Cohen, M.D., Ph.D.	Level 1 Auditorium
Breast Cancer Rebecca A. Shatsky, M.D.	Level 1 Room 141/143/145
Lung Cancer Sandip P. Patel, M.D.	Level 2 Rooms 215
Gastrointestinal Cancers Aaron M. Miller, M.D., Ph.D.	Level 2 Room 204

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Thank you to those who helped promote the summit

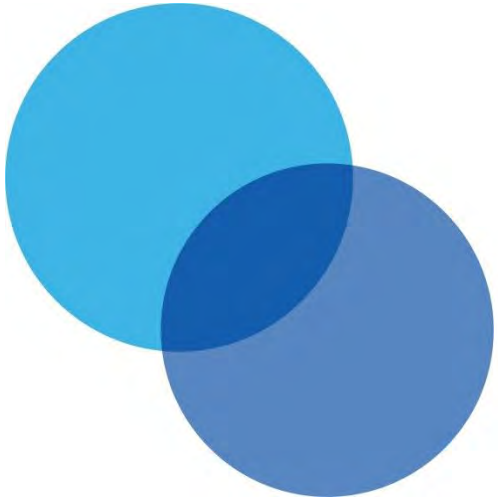
- Addario Lung Cancer Foundation
- American Cancer Society
- But Doctor I Hate Pink (Ann Silberman)
- Cancer Support Community
- CancerCare
- Colorectal Cancer Alliance
- Fight Colorectal Cancer
- FORCE
- Imerman Angels
- Leukemia & Lymphoma Society
- LUNGevity Foundation
- Let Life Happen (Barbara Jacoby)
- Patient Empowerment Network
- SHARE
- UC San Diego Moores Cancer Center
- Us TOO
- Young Survival Coalition

Thank You!

You will receive two emails after the summit:

1. **A survey** to share your feedback on the summit as well as insights into future programming.

2. **Information** from the Summit day, including this presentation and instructions on how to use our Clinical Trial Finder service.



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San Diego October 27, 2018